California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

NOTICE OF MEETING and AGENDA
Licensing Committee

DATE: **SEPTEMBER 20, 2006**
TIME: **9:30 a.m. – 12 noon**

Place: **Department of Consumer Affairs**
First Floor Hearing Room
1625 N. Market Boulevard
Sacramento, CA 95834

CONTACT PERSON: VIRGINIA HEROLD
(916) 574-7911

This committee meeting is open to the public and will be held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Candy Place at (916) 574-7912, at least five working days before the meeting.

Opportunities are provided for public comment on each agenda item. Board members who are not on the committee may also attend and comment.

Note: Pharmacists and pharmacy technicians who attend the full committee meeting can be awarded two hours of CE, in accordance with the board's CE policy. A maximum of four CE hours can be earned each year by attending the meetings of two different board committees.

Call to Order 9:30 a.m.

1. The Accreditation Council for Pharmacy Education Commemorates Its 75 Anniversary
2. Request to Add the Exam for the Certification of Pharmacy Technicians Developed by the Institute for the Certification of Pharmacy Technicians as Qualification Method for Pharmacy Technician Registration
3. Emergency Preparedness for California Pharmacy – Leading to the Development of an Action Plan by the Board of Pharmacy. Discussion and Presentation by Dana H. Grau, PharmD, Emergency Preparedness Office, California Department of Health Services
4. An Overview on 340B Drug Programs
5. Restrictions on the Transfer of California Pharmacist Licenses to Other States -- Memorandum dated March 31, 2006 from the National Association of Boards of Pharmacy
6. Foreign Pharmacy Graduate Equivalency Commission Certifications – Update on the Certification Process following Elimination of the Administration of the Test of Spoken English
7. Update on AB 595 (Negrete-McLeod) on Compounding by Pharmacies and Recent Action by the US District Court, Western District of Texas
8. Competency Committee Report

B. Adjournment 12 noon

Meeting materials will be on the board's Web site by September 10, 2006

State of California Department of Consumer Affairs

Memorandum

To: Licensing Committee **Date: Sept. 7, 2006**

From: Board of Pharmacy – Virginia Herold

Subject: ACPE Commemorates Its 75th Birthday

The board recently received a DVD highlighting the Accreditation Council for Pharmacy Education's 75th anniversary. The Licensing Committee will begin this meeting by viewing this approximately five minute DVD that highlights pharmacy and the activities of the ACPE.

ACCREDITATION COUNCIL FOR PHARMACY EDUCATION
20 North Clark Street, Suite 2500 • Chicago, Illinois 60602-5109 • www.acpe-accredit.org
312/664-3575 • FAX 312/664-4652 • E-mail: pvlasses@acpe-accredit.org

Peter H. Vlasses, Pharm.D., BCPS
Executive Director

July 20, 2006

Ms. Patricia Harris
NABP
c/o NABP
1600 Feehanville Drive
Mt. Prospect, IL 60056

Dear Ms. Harris:

This year marks the 75th Anniversary of ACPE's establishment as an organization. We celebrated this momentous milestone with a gala held in Chicago on June 24, 2006, attended by Mr. Carmen Catizone and Mr. Lawrence H. Mokhiber. In honor of our anniversary, Dr. Ulric Chung of our staff has put together a brief DVD detailing the history and growth of ACPE, a copy of which we are pleased to enclose. Highlighted in the DVD are the partnerships between the founding organizations that have made ACPE what it is today.

We are truly appreciative of the original vision of NABP and of its continued support through the appointing of members of your organization to our board and through the substantial financial support we receive on an annual basis. We would also like to express our thanks for the meaningful gifts presented to ACPE at the gala on behalf of the three founding organizations. ACPE looks forward to many more years of successful partnership with our founding and sponsoring organizations.

Sincerely,

Peter H. Vlasses, Pharm. D.

State of California Department of Consumer Affairs

Memorandum

To: **Licensing Committee** **Date: Sept. 7, 2006**

From: **Board of Pharmacy – Virginia Herold**

Subject: **Exam for the Certification of Pharmacy Technicians**

In California, individuals may become qualified for registration as pharmacy technicians by one of four means:

1. Possessing an associate's degree in pharmacy technology.
2. Completing a course of training specified by the board in regulations (accredited by ASHP, provided by the armed forces, or at least 240 hours of instruction covering specific topics).
3. Graduating from a school of pharmacy recognized by the board.
4. Being certified by the Pharmacy Technician Certification Board.

Recently, another pharmacy technician examination has been brought to the board's attention, the Exam for the Certification of Pharmacy Technicians (ExCPT). This exam has been developed by the Institute for the Certification of Pharmacy Technicians.

This examination is accepted by Connecticut, New Jersey, Minnesota, Oregon and Virginia as a qualifying route for registration for pharmacy technicians. According to material provided by the institute, the exam is a computer-based exam, which is administered in 700 locations nationwide. The National Community Pharmacists Association and the National Association of Chain Drug stores support use of the exam.

Kenneth W. Schafermeyer, Ph.D., RPh, will attend this Licensing Committee Meeting to provide an overview of the examination.

The committee may wish to explore whether it wishes to evaluate this examination for use in California, and if so, to direct staff to compile information about the exam and its validation.

Enclosed are a number of materials prepared by the Institute for the Certification of Pharmacy Technicians about this examination.

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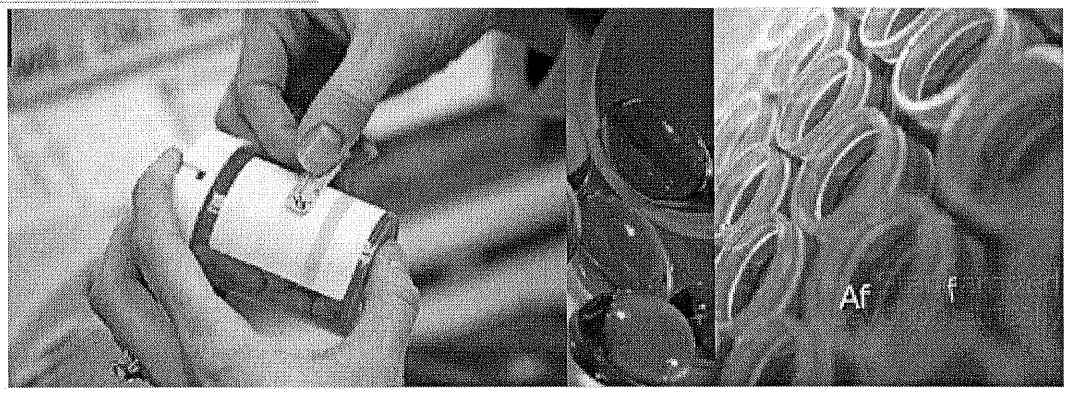

Welcome to the Institute for the Certification of Pharmacy Technicians

The purpose of the Exam for the Certification of Pharmacy Technicians (ExCPT) is to help ensure that a minimum knowledge base or competency is possessed by pharmacy technicians who assist pharmacists in the preparation of prescriptions. The ExCPT is nationally recognized by the National Community Pharmacists Association and the National Association of Chain Drug Stores as a psychometrically sound pharmacy technician certification exam.

The ExCPT is offered by the Institute for the Certification of Pharmacy Technicians (ICPT), which has succeeded a former organization known as the Institute for the Advancement of Community Pharmacy (IACP). With this name change comes an expanded staff and additional resources to enable the ExCPT to be offered nationwide.

Read More!

Virginia Pharmacy Techs

Are you a pharmacy technician who is working in the state of Virginia?

Read More!

News and Boa Approvals

Frequently asked que

In which states can pharmacy tech the ExCPT?

Connecticut

New Jersey

Minnesota

Oregon

Virginia

ICPT Exams Are Comp

The Pharmacy Certification Exam is computer at more than 700 testing nationwide. Using this option, cand the exam within a few days notice immediate test score results!

To view **PDF** documents you must install **Acrobat Reader**.

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Frequently Asked Questions

Question:
In which states can pharmacy technicians take the ExCPT?

Answer:
Pharmacy technicians can take the Exam for the Certification of Pharmacy Technic (ExCPT) in almost every state. There are only a few states that actually require te be certified and all of them allow the Board of Pharmacy to approve more than on certification exam. The ExCPT will be applying to these states for approval.

There are 24 states that do not recognize certification at all. Technicians and empl a choice as to which national certification test (ExCPT or PTCB), if any, that they w Pharmacy technicians certified by either exam have the same rights and responsib

The other states that allow an exemption to the pharmacist-to-technician ratio for certified technicians do NOT require all technicians to be certified and many, if not technicians in these states practice without being certified. Many technicians in the chose to be ExCPT certified in order to enhance their credentials or further their ca of these states recognize both the ExCPT and PTCB on an equal basis. We expect f soon and more to follow.

Currently, ExCPT-Certified pharmacy technicians are practicing in 23 states and th Columbia. For information about the requirements in your state, contact the ExCP Education at **ken@icptmail.org**.

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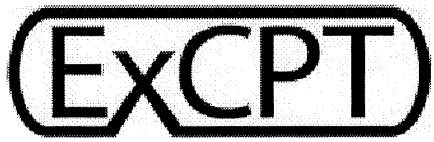
Specifications (v 1.4) of the Exam for the Certification of Pharmacy Technicians



Exam Specifications	
Eligibility	Candidates must be 18 or older with high school degree or GED. Candidates convicted of a drug-related felony may not be certified.
Test sites	Over 1,000 LaserGrade Test Centers located throughout the country.
Number of times per year that exam is offered	Over 300
Deadline for exam registration	Usually less than 48 hours
Deadline for notification of change of exam time or location	24 hours
Exam format	Secure computer-based exam
Number of questions	100 multiple-choice questions with choices a-e. (No questions have distracters worded "all the above.")
Passing score	Scaled scores range from 200 to 500. A 390 or higher is needed to pass.
Quality Assurance	
Exam based on comprehensive job analysis	Yes
Advice and oversight by panel of experts	Yes
Meets standards of the American Educational Research Association, American Psychological Association and National Council on Measurement in Education, *Standards for Educational and Psychological Testing*	Yes
Audited by independent experts in psychometrics	Yes
Exam items written by a panel of expert item writers	Yes
All test items field tested prior to use	Yes
Board given evidence of reliability	Yes
Board given evidence of validity	Yes

Exam Security	
Eligibility verified at time of exam.	Pre-registration required; approved identification must be shown at test center.
Exam items changed on periodic basis	Yes
Proctors thoroughly training to follow procedures and for handling emergency situations.	Yes
Stringent computer encryption programming used	Yes
Exams sent to testing site before exam	No
Extra printed exams that must be accounted for and destroyed if not used	Not necessary because of computer-based exam
Services for Candidates	
Diagnostic report offered to unsuccessful candidates	Yes
Candidates with disabilities accommodated in compliance with ADA	Yes
Study guide available on website	Yes
Practice exam questions Available free of charge	Yes
Website for exam information	Yes
Exam results reported to candidate	Immediate notification
Recertification	Required every two years. 20 hours of pharmacy-related continuing education (including at least one hour of law) required
Services for Board of Pharmacy	
Provides Board with performance bond	Yes
State-specific questions offered	Optional
Results of item analysis and test statistics reported to Board on a periodic basis.	Yes
Exam results reported directly to the Board of Pharmacy	Yes. Available via a secured private web site for the Boards of Pharmacy
Criminal background checks	Available for extra fee if Board elects

About ICPT

The Institute for the Certification of Pharmacy Technicians (ICPT) is operated by pharmacists for the pharmacy profession. The purpose of the Exam for the Certification of Pharmacy Technicians (ExCPT) is to help ensure that a minimum knowledge base or competency is possessed by pharmacy technicians who assist pharmacists in the preparation of prescriptions. The ExCPT is nationally recognized by the National Community Pharmacists Association and the National Association of Chain Drug Stores as a psychometrically sound pharmacy technician certification exam.

Please feel free to contact ICPT if you have any questions.

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Office hours: 9am-4pm CST.

Web site: www.nationaltechexam.org

Email: bette@icptmail.org
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ICPT Exams Are Now Computerized!

ICPT is pleased to announce that the Pharmacy Certification Exam is now available computer at more than 700 testing centers nationwide. Using this option, test take immediate test score results!

LaserGrade, one of the largest test center networks in the country, will administer Most centers are open six days a week for your added convenience! For more info find a test center near you or register to test, visit LaserGrade online at **www.LaserGrade.com** or call 800.211.2754.

Pricing:
$95 for the Pharmacy Exam
(Certificate will be delivered within 4-6 weeks upon successful completion of the e

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Privacy Policy Statement

This is the web site of **Institute for the Certification of Pharmacy Technician**

Our postal address is
1816 Woodmark Rd
St. Louis, MO 63131

We can be reached via e-mail at **bette@icptmail.org** or you can reach us by tele
314-442-6775.

For each visitor to our Website, our Web server automatically recognizes only the domain name, but not the e-mail address (where possible). We do, however, colle mail addresses of those who communicate with us via e-mail.

The information we collect is used to improve the content of our Website, is not sh other organizations and is disclosed when legally required to do so, at the request governmental authorities conducting an investigation, to verify or enforce compliai policies governing our Website and applicable laws, or to protect against misuse o unauthorized use of our Website.

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NEWS RELEASE

The Connecticut Commission on Pharmacy Approves the ExCPT Exam.

(Hartford, CT, July, 2006 – For Immediate Release) After an exhaustive 10-month investigation, **the Connecticut Board of Pharmacy confirmed on July 26 that the Exam for the Certification of Pharmacy Technicians (ExCPT) was equivalent to the PTCB exam** and approved it in the state of Connecticut. The Commission found that "The ExCPT exam is psychometrically sound, legally defensible and equivalent to the PTCB." Steven Beaudin, a public member of the Commission, said, "I'm glad that we now have two certification exams in Connecticut. Competition is a good thing."

To determine equivalency, the Commission compared, among other things, the content and rigor of the PTCB and ExCPT exams as well as the organization and governance of both organizations. The policies and procedures used for the practice analyses, test blueprints, item writing procedures, test assembly procedures, scoring, reports, security and quality assurance procedures were found to be equivalent. The Commission intends to continue monitoring and will compare both exams again in a year.

Kenneth W. Schafermeyer, Ph.D., R.P.h., Director of Education for the Institute for the Certification of Pharmacy Technicians (the sponsor of the ExCPT) said, "We are very pleased with this decision as we move forward with approval process of the ExCPT Exam in all applicable states and to be recognized by all pharmacy employers. The ExCPT Exam is offered in all LaserGrade testing centers 325+ days a year in every state throughout the U.S. at a technician-friendly cost of $95. We intend to provide every pharmacy technician superior educational and professional services as their career develops."

Connecticut regulations allow a 2:1 ratio of technicians to pharmacists but authorize the pharmacist to supervise one additional technician if he or she is certified. According to Connecticut statutes, "The department shall, upon authorization of the commission, certify as a pharmacy technician any person who meets the requirements for registration as a pharmacy technician . . . who holds a certification from the Pharmacy Technician Certification Board or any other equivalent pharmacy technician certification program approved by the department."

- more -

About ICPT

The Institute for the Certification of Pharmacy Technicians (ICPT) is operated by pharmacists for the pharmacy profession. The purpose of the Exam for the Certification of Pharmacy Technicians (ExCPT) is to help ensure that a minimum knowledge base or competency is possessed by pharmacy technicians who assist pharmacists in the preparation of prescriptions. The ExCPT is nationally recognized by the National Community Pharmacists Association and the National Association of Chain Drug Stores as a psychometrically sound pharmacy technician certification exam. The exam is offered in all 50 states and the District of Columbia.

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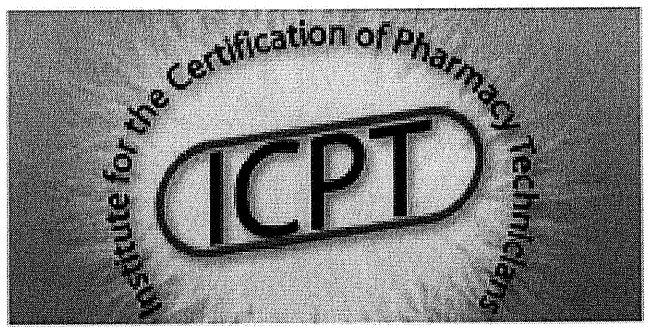

Institute for the Certification of Pharmacy Technicians

Report to Boards of Pharmacy

August 2006

The following report is based on information provided by the Institute for the Certification of Pharmacy Technicians in response to a Request for Information (RIF) from the Connecticut Commission on Pharmacy. After an exhaustive 10-month investigation, **the Connecticut Board of Pharmacy confirmed on July 26 that the Exam for the Certification of Pharmacy Technicians (ExCPT) was equivalent to the PTCB exam** and approved it in the state of Connecticut. Despite strong opposition from our competitor and its financial partners, the Commission still found that "The ExCPT exam is psychometrically sound, legally defensible and equivalent to the PTCB."

To determine equivalency, the Commission compared, among other things, the content and rigor of the exams as well as the organization and governance of the two companies, the policies and procedures used for the practice analyses, test blueprints, item writing procedures, test assembly procedures, scoring, reports, security and quality assurance procedures. This information is included in this report.

After careful review, I am confident that all Boards of Pharmacy will reach the same conclusion as the Connecticut Commission on Pharmacy that **the ExCPT is at least equivalent to the PTCB in rigor and superior with regard to access and cost.**

Kenneth W. Schafermeyer, R.Ph., Ph.D.
Director of Education
ken@icptmail.org
314-609-1073

List of Attachments

Institute for the Certification of Pharmacy Technicians

Report to Boards of Pharmacy
August 2006

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Report to Boards of Pharmacy

regarding

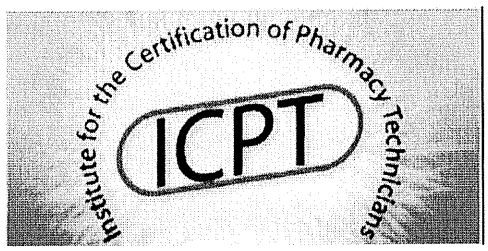
The Exam for the Certification of Pharmacy Technicians

ExCPT

provided by

The Institute for the Certification of Pharmacy Technicians

August 2006



All information is accurate as of the date written and may be subject to change. Additional details are available from the ICPT and LaserGrade websites. All questions about the ECPT should be referred to Kenneth W. Schafermeyer, R.Ph., Ph.D., Director of Education: ken@icptmail.org or 314-609-1073.

I. Governance

A. *Policies and Procedures*

ICPT policies and procedures are attached under Appendix1.

B. *Individuals or corporations having a financial interest in the test providers' organization, including providers of grants or financial support.*

The National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA) have a financial interest in the ExCPT. Depending on volume and expenses, these two organizations will split royalties that will range from 0% to 35% of exam fees. At this point, the royalties are still at 0%. ICPT's partner, LaserGrade receives approximately 42% of exam revenues.

II. Examination Generation, Validation, and Administration Process

A. *Practice analysis*

1. *Date performed.* The practice analysis for the ExCPT was completed in August 2005. A previous practice analysis was conducted for the Virginia Board of Pharmacy in February, 2003.

2. *Methodologies employed.* A survey questionnaire was mailed to a stratified random sample of 630 individuals (420 pharmacy managers and 210 pharmacy technicians). A reminder postcard and follow-up survey were also sent to non-respondents. Respondents were given a list of over 50 job functions and asked to indicate: (1) the importance of each pharmacy technician function with regard to promoting patient health and safety (with a Likert Scale responses ranging from very important [5] to not important [1]); (2) the frequency that pharmacy technicians perform each function on an average day; and (3) the relative amount of time that pharmacy technicians spend on each function (with a Likert Scale responses ranging from high to low). Fifty-six surveys were returned because of bad addresses. Of the 574 surveys delivered, 308 were returned but 20 were discarded as unusable. The overall response rate, therefore was 50.2%. The results were tabulated and ranked in descending order.

3. *Practice settings examined.* The pharmacy technician functions covered in the practice analysis included functions performed in all practice settings, including community and institutional practice.

Respondents practiced in a variety of practice settings: community (66%), hospital (23%), long-term care (8%); and other (3%).

4. *Conclusions or final determinations.* The ranking of the various practice functions is attached under Appendix2. These results were used by the Expert Panel, along with input from stakeholders, was used to design the exam blueprint.

   Although pharmacy technicians typically ranked most functions as slightly more important and performed slightly more frequently than did pharmacy managers, the rank order for the various functions was essentially the same for both groups. As would be expected, practitioners practicing in a given setting tended to value their functions as more important than those not practicing in that setting. Therefore, the results for practitioners from each practice setting were compared to assure that functions important to one type of setting were not unduly outweighed by those functions deemed to be more important by respondents from other types of settings. The exam blueprint, therefore, reflects pharmacy technician functions relevant to all major practice settings.

B. Test blueprint/plan

1. *Test purpose.* The purpose of the Exam for the Certification of Pharmacy Technicians (ExCPT) is to encourage pharmacy technicians to improve their knowledge and skills and to help ensure that a minimum knowledge base or competency is possessed by pharmacy technicians who assist pharmacists in the preparation of prescriptions.

2. *Target audience.* The target group for the ExCPT is pharmacy technicians from all practice settings throughout the United States. Stakeholders include individuals, companies, associations and government agencies that employ, supervise, train, regulate or receive services from pharmacy technicians.

3. *Covered content or performance areas.* Please see the Exam Blueprint at Appendix3.

4. *Number and types of questions to be written for each content or performance area.* Please see the Exam Blueprint at Appendix3.

5. *Scoring.* The ExCPT is scored immediately and successful candidates are given an official report by LaserGrade indicating that they passed the ExCPT immediately after completing the exam. Candidates may use this report to provide evidence to

employers or regulatory boards that they passed the ExCPT and are a certified pharmacy technician.

The purpose of the exam is to provide summative assessment (i.e., to determine whether an individual has achieved a certain level of competency). It is not designed for formative assessment (i.e., to give the candidate feedback). ICPT does, however, provide diagnostic reports to help unsuccessful candidates focus their study time so they can successfully retake the exam. Candidates can also get some formative feedback by answering the practice problems that are offered on the ICPT website.

Candidates who do not pass the ExCPT will be allowed to retake the exam after four weeks. Since there are multiple versions of the ExCPT, candidates who take retake the exam will receive a different, but equivalent, set of questions.

The passing score is established by the ICPT Expert Panel based on a standard of performance that experts in the profession have determined are acceptable for this certification program. Specifically, the Expert Panel uses a modified Angoff procedure (descried later in this document) to determine the passing score. The passing score is not based on a curve.

6. *Test administration method.* The ExCPT is a secure, computer-based exam offered during business hours and some evenings and weekends at over 1,000 LaserGrade Testing Centers throughout the United States. Candidates may register by calling the LaserGrade toll-free number. Candidate identification is verified at the LaserGrade Testing Center at the time of the test. The candidates have two hours to answer 110 multiple-choice questions. One question is presented on the screen at a time. Candidates may mark the answer or they can skip questions and come back later. Final answers are submitted when the candidate is finished and results are given immediately. A demonstration of the computer format used for exams administered by LaserGrade is shown on the LaserGrade website at www.lasergrade.com.

Candidates are given an opportunity to comment on any question that they believe is ambiguous, inaccurate or deficient. Candidates are also asked to complete a brief survey at the end of the exam to rate the exam registration procedures, the testing facility and general satisfaction with the testing experience. This information is reviewed by the Director of Education and referred t the Expert Panel for recommendations if necessary.

7. *Desired psychometric characteristics.* All items in the test bank are pretested to examine reliability, discrimination and validity. Items used on each exam are also examined to assure proper performance. Following is a discussion the desired characteristics with regard to reliability, discrimination and validity.

Reliability. Reliability refers to the accuracy (consistency and stability) of measurement by a test.[1] In other words, reliability is the extent to which test scores are free from errors in the measurement process. The most commonly used statistical index is the reliability coefficient. In numerical value, reliability coefficients are always between .00 and .99.[2] Values of 0.80 and above are considered good, but the closer the value of the reliability coefficient to the upper limit, the less measurement error and the greater the reliability. The statistical test used to produce the reliability coefficient for the ExCPT is the Kuder Richardson 20. This statistic provides an *overall measure* of the ability of test items to discriminate between high-scoring students and low-scoring students. (To test the ability of *individual* items to discriminate between high-scoring students and low-scoring students, discrimination analysis (see below) is used.) The formula for Kuder Richardson 20 is as follows:

$$KR = (N/(N-1)) * ((V - SUM (p_i q_i))/V)$$

KR = Kuder Richardson 20
N = Number of items in the test
V = Variance of the raw scores, or (Standard Deviation)^2
p_i = Proportion of correct answers of question i, or (number of correct answers/total number of responses)
q_i = proportion of incorrect answers of question i, or (i - p)

The reliability coefficient for the ExCPT has consistently remained at 0.90 or higher. This provides strong evidence that the ExCPT meets the criteria for reliability.

Discrimination Analysis. Discrimination analysis is a type of multiple-regression analysis commonly used in calculating test statistics for multiple-choice examinations. In this case, one

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1 Isaac S and Michael WB, *Handbook in Research and Evaluation, Second Edition* (San Diego: Edits Publishers, 1985): 123-126.

2 National Computer Systems, *MicroTEST Score II User's Guide* (Minneapolis: National Computer Systems, 1988): 5-11, B-6.

measure of the performance of an individual item is the discrimination – the extent to which persons who perform well on the entire exam do well on an individual item, and vice versa.[3] The discrimination analysis separates individuals into quartiles according to their scores. The high quartile and low quartile are then compared for each exam item. In other words, to discriminate properly between people who will do well on an exam and those who do not, individuals selecting the correct answer for a particular question should show a modest to high correlation with the "pass rate" for the overall exam. Likewise, an exam item discriminates properly if those individuals selecting incorrect answers correlate negatively with the pass rate for the overall exam. The formula used to calculate the discrimination index for each response alternative is as follows:

$DI = (a - b) / c$

DI = Discrimination Index
a = Response frequency of the upper quartile
b = Response frequency of the lower quartile
c = Number of respondents in the upper quartile[4]

Discrimination scores range from -1.0 to 1.0.[5] For each question correct answers should have a positive discrimination (items greater than 0.1 are generally considered acceptable; 2.0 or higher is considered good) and incorrect answers should have a zero or negative discrimination. An exception to this rule occurs when a large percentage of examinees (e.g., over 90 percent) answer a question correctly. In this case, the question would not be able to discriminate much and, therefore, the discrimination index would be close to zero. Since there should be some variance in the degree of difficulty of the individual items in a given exam, it can be expected that there may be some questions on a minimum competency exam that will be answered correctly by the great majority of examinees and, consequently, would have low discrimination indices. Items that are answered correctly by more than 90 percent of the candidates, however, are generally replaced in order to encourage more discrimination among candidates.

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3 Norman G and Streiner D, *Biostatistics: The Bare Essentials* (St. Louis: Mosby, 1994); 178.

4 National Computer Systems, *MicroTEST Score II User's Guide* (Minneapolis: National Computer Systems, 1988): B-4.

5 Kerlinger FN, *Foundations of Behavioral Research, Third Edition* (New York: Holt, Rinehart and Winston, Inc., 1986): 562.

When reviewing the computerized item analysis of pilot exams, ICPT looks for several types of problems. First, the discrimination analysis is studied to ensure there are no questions in which the correct answer has a negative discrimination index. Second, the statistics are studied further to assure that no distracters (i.e., the answer choices that are not correct) have a positive discrimination index. If either of these two problems were to occur, the exam item will either be revised and retested or deleted from the test bank. Thirdly, ICPT looks at degree of difficulty. A generally accepted method of exam construction is known as the "rule of thirds" – one third of the questions would be relatively difficult, one-third moderate difficulty and one-third easier. Effort is made to achieve an acceptable balance of item difficulty.

Validity. There are three major types of validity measurements: (1) content validity, (2) criterion validity and (3) construct validity. Content validity is often referred to as "face validity." This measurement is an index of whether the exam is really measuring what it claims to measure and whether the exam provides an adequate sample of that kind of behavior.[6] Content validity is ultimately a matter of judgment. In the case of the ExCPT, content validity was determined by the Expert Panel. It was the professional judgment of the Panel members that the ExCPT adequately measures the content needed to work as a pharmacy technician. The opinion of members of the Stakeholder's Council will be sought and considered on an on-going basis.

The second type of validity, criterion validity, is studied by comparing test or scale scores on the new test with one or more external variables, or criteria, known or believed to measure the attribute under study.[7] Measuring the same skill with two different tests should produce the same results (i.e., pass or fail) if there is criterion validity. Employers using the ExCPT have indicated that those who pass the ExCPT perform adequately in practice and those who fail do not and often need additional training. Periodic stakeholders meetings are scheduled to determine, in part, whether testing content continues to be valid for the work environment of pharmacy technicians.

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6 Bailey KD, *Methods of Social Research, Third Edition* (New York: The Free Press, 1987): 67-68.

7 Kerlinger FN, *Foundations of Behavioral Research, Third Edition* (New York: Holt, Rinehart and Winston, Inc., 1986): 418-419.

The third type, of validity, construct validity, seeks to explain individual differences in test scores. For example, it would not be expected that exam scores would vary according to age or gender; they would, however, be expected to vary according to experience or level of education. By collecting demographic data from each ExCPT examinee, it was determined that correlations among exam scores and age, gender, practice site, hours worked per week and educational level were not statistically significant. There was, however, a moderate relationship between test performance and years of practice when comparing less than one year to more than one year.

One way that the Test of English as a Foreign Language (TOEFL) measures construct validity of its exam as a measure of English language proficiency is to compare scores of native speakers to those of nonnative speakers. Native speakers find the TOEFL quite easy and their scores are homogeneously high; and a high proportion of them earned maximum or near-maximum scores. Performance of nonnative examinees was lower and more widely distributed.[8] A comparison of scores of pharmacists with those of pharmacy technicians would show uniformly high scores by pharmacists (compared to the lower and more widely distributed scores of technicians) and this would provide additional evidence of construct validity.

8. *Competency statements*. Please see the statements included in the practice analysis and the content of the exam blueprint (Tabs 2 and 3, respectively).

C. *Item writing procedures*

1. *Item writers and their respective areas of expertise*. Item writers include pharmacy and pharmacy technician educators and practitioners who have practiced in many different states and in many different practice settings including community, hospital, long-term care and home health care. A list of item writers is included under Appendix4.

2. *Any item writing training administered to writers*. Item writers and Expert Panel members are given written materials and oral instructions on writing acceptable multiple-choice items. An exercise as a part of this training involves providing these individuals with a set of multiple-choice practice questions for

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8 Educational Testing Service, *TOEFL Test & Score Manual* (Princeton, NJ: Educational Testing Service, 1997): 36.

critique and discussion. The guidelines used in this training are from a well-known text by Gronlund.[9]

3. *Qualifications of trainers.* The trainers were Drs. Kenneth Schafermeyer and Dana Hammer. Both have extensive experience at educational design and assessments. CVs of both are available on request. Reference letters for Dr. Hammer are included under Appendix5.

4. *Description of testing standards employed.* The ExCPT follows and meets standards of the American Educational Research Association, American Psychological Association and National Council on Measurement in Education, *Standards for Educational and Psychological Testing.* The ExCPT also employs the standards established for certification programs by the National Commission for Certifying Agencies (NCCA).

D. ***Exam items and questions***

1. *Test format.* The ExCPT is a secure, psychometrically sound computer-based exam that consists of 110 multiple-choice questions, of which ten are pretest questions that are not scored.

2. *Item validation process.* This was discussed in the previous section titled "Desired Psychometric Characteristics."

3. *Field testing and review process.* This process is discussed in the following section titled "New item field testing procedures."

4. *Item pool depth and rotation.* The testbank consists of just over 3,000 items. New items are being added on a regular basis with about 300 new items expected to be added during the last half of this year. With three versions of the exam, any candidates retaking the exam would be assured of seeing a different set of questions the following month when they are eligible to register again. At least 20 questions are changed each month. Those items that are rotated off the exam may be reused at some point. To avoid overexposure, items will be retired as new items are adopted. All versions of the exam, however, will be consistent with the exam blueprint. In addition to rotating and retiring test items, the order of test items and answers are scrambled and numbers for calculation questions are changed on a frequent basis.

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9 Gronlund NE, *How to Make Achievement Tests and Assessments, Fifth Edition* (Boston: Allyn and Bacon, 1993).

E. *Item analysis*

1. *New item field testing procedures.* Pretesting new questions before they are used as scored questions on the ExCPT is necessary to assure that all items perform properly and that new versions of the exam can be created in the future. As with all standardized tests, the ExCPT contains some questions that are being pretested for possible use on future exams. Specifically, the ExCPT consists of 110 questions, of which ten are pretest questions that are not scored. The pretest items are randomly interspersed throughout the exam and are not identified for the candidate in order to assure that test statistics are valid. When a sufficient amount of data is obtained (usually 50 to 100 data elements), these pretest questions are pulled from the ExCPT and new pretest questions are substituted. All pretest items are analyzed carefully for difficulty, reliability, discrimination and validity and are approved by the Expert Panel before they are used as scored questions on future versions of the ExCPT.

2. *Item performance analysis method.* All items are carefully reviewed through a process known as an item analysis. This item analysis consists of statistical procedures to determine the difficulty, discrimination, reliability and validity of each item before they are used as scored questions in the ExCPT and again on a regular basis while items are being used. A description of these statistical procedures was described in the previous section titled "Desired Psychometric Characteristics."

3. *Item ongoing performance review and recall process.* The Director of Education receives weekly reports from LaserGrade indicating the score earned on each exam taken during the week as well as the answers given for each item – both scored items and pretest items. Results are reviewed for unexpected difficulty, unusual patterns and other potential problems. For example, if a new item had been miskeyed, the problem would be detected immediately and scores adjusted accordingly. Items that are determined by the Director of Education to be too easy, too difficult, outdated or fail to discriminate properly are either removed from the testbank for future editing or retired. The Expert Panel also reviews performance of the items on a regular basis and can determine whether certain items should be recalled. As explained previously, items are rotated often but are eventually retired and replaced with new items.

F. *Examination review committee*

1. *Member names.* The members of the Expert Panel are included under Appendix6.

2. *Areas of expertise.* Please see Appendix6.

3. *Current employment.* Please see Appendix6.

4. *Tenure on the Committee.* Individuals on the Expert Panel serve three-year terms with terms staggered to assure continuity.

G. *Description of test assembly procedures*

1. *Exam consistency between administrations.* To protect the integrity of the exam, multiple versions of the ExCPT are used and the sample of questions taken from the test bank changes continuously as well. Because different administrations of the ExCPT are made up of different combinations of questions, it is important to assure that these different versions provide an equal challenge to everyone. The careful selection of items assures that different versions of the exam test the same content areas. The Expert Panel establishes the passing score using the modified Angoff procedure in which each panelist independently estimates the percentage of qualified candidates who would correctly answer each item. The panelists' ratings are averaged to determine the passing score (also known as the "cut score"). With a relatively large panel of ten members, it is advisable to decrease variance by deleting the extreme high and extreme low estimates. This, of course, does not affect the median score—only the variance. The overall passing score is determined by averaging the individual ratings. Although care is taken to make each version equivalent, the ExCPT is now using statistical methods to equate and scale exam scores.

   Equating is essentially a statistical method of selecting the raw score on each test that would provide the same probability of passing. In other words, it is a way of calibrating different versions of the exam to assure that they provide an equal challenge. For example, a raw score of 75 may be determined to be a passing score on one version of the exam and a 74 may be determined to be the equivalent passing score on a more difficult version.

   A scale is a score-reporting technique that translates the different raw scores into a standard score. For example, the scores that may be earned on the ExCPT range from 200 to 500 and the passing score is 390. The minimum passing raw scores are then converted

to 390 for all versions of the exam. If two different versions of the exam have different cut scores (e.g., a raw score of 75 on one version and a raw score of 74 on another) then both are converted so that 390 is the passing score. Reporting only raw scores could cause confusion because the results of one test administration may be difficult to compare with another that does not have exactly the same difficulty or same cut score. Equating and scaling procedures are used in most certification programs because they are easy and reliable, commonly accepted as standard procedures in certification programs, psychometrically sound and are legally defensible.

2. *Correlation of the passing score with the practice analysis findings*. Scores for each content area of the exam are reviewed to determine which areas are most difficult. Experience with the ExCPT shows that the most difficult area for candidates continues to be pharmacy calculations. Fortunately, candidates performed better on those content areas that were rated higher in the practice analysis in terms of criticality and frequency of performance. ICPT is collecting performance data in order to encourage candidates to give particular attention to studying the more difficult content areas that were rated high in the practice analysis.

3. *Effective discrimination between candidates who perform well and those who perform poorly*. Evidence reported in the item analysis helps assure that items discriminate properly so that the exam does too. The cut score effectively discriminates between the group which performed satisfactorily from that which did not.

4. *Psychometric standards employed in exam assembly*. The ExCPT employs the both the APA and NCCA standards discussed previously. These standards require certain procedures to be followed, including the practice analysis, Expert Panel, item writing, item review, item pretesting and item writing, which were all described previously.

H. *Test form*

1. *Testing media design*. The ExCPT is a secure, proctored, computer-based exam offered at LaserGrade Testing Centers throughout the United States.

2. *Number of test forms employed per administration*. Three equated versions of the ExCPT are available. The exam form to be administered to a given candidate will be randomly selected.

Unsuccessful candidates retaking the ExCPT will be given a different version.

3. *Method of assuring exam construction consistency between test forms or computer iterations.* All exam forms are equated to assure that they provide the same challenge to all candidates. As explained previously in Section I-G (1), establishing cut scores, equating and scaling are used to assure continuity. The item analysis provides statistics demonstrating that different forms of the exam are consistent with regard to the challenge presented to candidates.

4. *Security procedures to preserve test integrity and limit item exposure.* Policies and procedures regarding confidentiality and cheating are outlined in Section 7 of the ICPT Policies and Procedures. (Please see Appendix1.) Policies and procedures related to registration, identification, and security procedures at the LaserGrade Testing Center are explained in Section 8 of the ICPT Policies and Procedures. (Please see Appendix1.) LaserGrade requirements for security and supervision at the Test Centers are outlined in Section 5 of the "LaserGrade Testing Center Requirements" found under Appendix7.

   The computer-based exam available through LaserGrade is far more secure than a paper-and-pencil exam. The LaserGrade Test Center Specialist must enter an individual password to gain access to the on-site computer. The text for the questions and the candidate's answers are encrypted and sent to the Test Center computer after the candidate is admitted and shows proper identification. When the candidate has completed the ExCPT, the test report is printed and the candidate's encrypted results are sent to LaserGrade and the Test Center's copy of the exam is written over and erased. Exams are never left on the Test Center Computers. The exam also times out after two hours.

   All individuals associated with the ExCPT, including members of the Board of Directors, item writers, Expert Panel members and staff sign a confidentiality agreement that requires them to hold any and all information about items on the ExCPT completely confidential. This agreement remains in effect for three years after the individual's service to ICPT.

I. *Scoring*

1. *Description of scoring employed.* Scoring is described in Sections II-B (5), II-B (7), and II-G above and in Section 9 of the ICPT Policies and Procedures. This topic was discussed previously.

2. *Rationale for scoring type used.* This topic was also discussed previously in Section II-G (1). This commonly used scoring procedure is consistent with standards for certification programs and is legally defensible.

III. Reports

ICPT creates a number of reports; some of which are public and some fomr internal purposes only. The public reports will be posted on the ICPT website and the private reports are used by the board of directors, Expert Panel and Stakeholders Council as needed.

A. *Passing score*

1. *Frequency of report.* As described previously, ICPT receives weekly score reports from LaserGrade, which are carefully reviewed by the Director of Education. Results are compared to the results from the cut score analysis (described previously) to assure that exams and individual items are performing as expected. Bimonthly score reports include test statistics such as the mean, median, pass rate, range, minimum, maximum, standard deviation, standard error, reliability coefficient and reliability index. Results are reported to the Expert Panel, which helps provide oversight and quality assurance. The overall pass rate will be published on the IPCT website.

2. *Process for determining passing score.* This topic was described previously in Sections II-B (5) and II-G above.

B. *Technical reports*

Technical reports used to monitor the exam, establish the cut scores and analyze results are available to stakeholders as needed.

1. *Frequency of report.* Update reports are received by ICPT weekly; complete statistical analyses are received on an as-needed basis – no less than bimonthly. Additional special reports are received on an as-requested basis. Reports on pass scores and general exam information are reported on the ICPT website and other relevant

information will be reported to the board, Expert Panel and Stakeholders Council as needed.

2. *Administration operational information.* Relevant operational information such as policies and procedures, staff contact information, Expert Panel members, etc. will be kept up to date on the website.

3. *Description of test assembly procedures.* The procedure used to assemble the test will be published on the website. A database program for the test bank will be available for internal use only and used to categorize questions according to topic and degree of difficulty. This database also records, among other things, a number for each item, the item writer, the date adopted, the date pretested, the difficulty, discrimination, versions of the exam that used the item, and an indicator of "bad pairs" (i.e., the number of other items that should not appear on the same exam). This database helps the Expert Panel to assemble new versions of the exam in compliance with the test blueprint. The database also helps the Expert Panel to record item performance. An analysis of individual ratings under the modified Angoff method is used to help establish passing scores.

4. *Reliability and validity information.* Reliability data is included with each complete statistical report and item analysis that is received at least bimonthly. Procedures for establishing validity are described above.

5. *Test equating methods.* The procedures for equating exams was described in Section II-G (1) and will be reported on the ICPT website. The weekly reports received from LaserGrade are reviewed carefully by the Director of Education and Expert Panel to assure that the exam and exam items are performing as expected. The complete statistical report and item analysis is also checked to assure that the equating method is working properly.

6. *Scoring tables and procedures.* Although the procedures are published on the website, the actual scoring tables for developing passing scores are used internally by the Expert Panel.

7. *Statistical summary information.* Pass rates and reliability statistics for the ExCPT will be published continuously on the ICPT website. Information about individual items, of course, are only used internally.

C. *Score reports to examinees and the Commission*

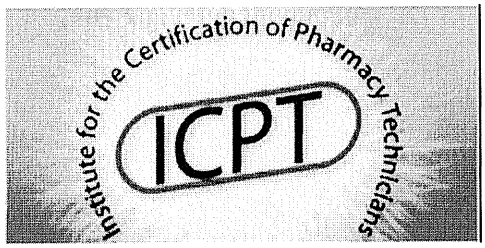
1. *Availability of diagnostic information for failing candidates.* Diagnostic reports are provided to unsuccessful candidates immediately upon completion of the ExCPT. This report indicates those content areas that should be studied more carefully by the candidate.

2. *Possibilities for Commission report customization.* Boards of pharmacy have access to a password-protected website that contains a complete set of up-to-date ExCPT records. A board of pharmacy staff member will be given a password and training to check the website for score reports and exam statistics. Although the database allows boards to make queries and print reports, ICPT is committed to providing information needed by the board and will consider producing periodic or special reports as needed.

3. *Pass/fail report to the Commission.* This information is also included in the secure online website and is updated daily.

4. *Frequency of reporting to the Commission.* The board can access the database whenever it wants and as often as it wants.

Appendix 1



Institute for the Certification of Pharmacy Technicians

Policies and Procedures

1. Eligibity Requirments

To be eligible to take the *ExCPT*, a candidate must: (1) be at least 18 years of age, (2) have a high school diploma or GED and (3) have never been convicted of a felony. Candidates will be required to provide an attestation stating that they meet these criteria and recognize that ICPT will revoke certification if any false information is provided by the candidate. ICPT reserves the right to investigate criminal background and verify candidate eligibility. Candidates must provide a government-issued photo identification at the time of the exam to verify identity.

2. Registration

Contacting LaserGrade. The *ExCPT* is offered over 300 days per year at over 1,000 LaserGrade Testing Centers throughout the United States. Candidates may register by calling the LaserGrade toll-free number 1-800-211-2754 to arrange a test date, time and location. By providing a zip code, the candidate will be informed of the closest LaserGrade Testing Centers. Alternatively, these locations can be found on the Web at www.lasergrade.com. Exams can usually be taken within 24 to 48 hours of registration.

Information required. Candidates must give their full name, address, Social Security Number, telephone number, email address (if applicable) and demographic information such as date of birth, gender, employer, type of practice site, type of training, years of practice and hours worked per week. Candidates should also indicate whether they qualify for special accommodations under the Americans with Disabilities Act. (See the following section.) These data are used to analyze test results and produce reports. Date of birth also helps verify identification at the test center.

Payment. The *ExCPT* costs $95 and it is payable by credit card at the time the candidate calls LaserGrade. Candidates who do not have credit cards can send LaserGrade a check or money order. When the check clears LaserGrade will contact the individual to arrange the test date. Employers may prepay for a specified number of candidates by making

arrangements directly with LaserGrade. Registered candidates who need to change an exam time for any reason must contact the LaserGrade call center at least 24 hours in advance to reschedule or cancel an exam without penalty.

3. Americans with Disabilities Act

General policy. Candidates with documented disabilities (including learning disabilities, reading disabilities, visual impairment, hearing impairment, or other physical or mental disabilities) will be given special accommodations upon request, in conformance with the Americans with Disabilities Act (ADA).

Procedure for requesting special accommodations. Documentation must be provided at the time of the request and must provide a specific description of the candidate's needs. Candidates must indicate the name of a physician or other professional who can verify the disability or provide further information in support of the request. The candidate may include a letter from an appropriate professional on official stationalry that provides evidence of a prior diagnosis or accommodation (e.g., special education services). Previous school records may also be submitted to document a disability. This documentation letter must describe the specific disability/diagnosis, the approximate date when the disability was first diagnosed, the method used to confirm the diagnosis, a brief description of the disability, and the type of accommodation needed by the candidate. The letter must be signed by the professional. Candidates requesting accommodation because of an emotional disability must have a SSM-IV classification of the diagnosis specified in the letter.

The candidate will need to provide authorization for the physician or other professional to share protected health information as described in the Heath Insurance Portability and Accountability Act (HIPAA). This physician or other professional may be contacted by ICPT to verify information or provide clarification of any information with regard to the disability or testing needs. ICPT will respond to the candidate within ten business days. Some states may also require approval by the Board of Pharmacy.

ICPT will respond to the request for accommodation as quickly as possible; generally within 10 business days of the request.

4. Affirmative Action

The ICPT and LaserGrade Testing Centers do not discriminate against any individual because of age, disability, gender, national origin, race, religion, sexual orientation, or veteran status. ICPT and LaserGrade endorse and adhere to the principles of equal opportunity.

5. Cancellation of Scheduled Exam

Notification by candidate. Candidates who are unable to take the ExCPT at the scheduled time should notify LaserGrade at least 24 hours in advance to avoid penalties. Refunds are not provided but credit will be given for a future exam appointment. If an

exam appointment is cancelled by the candidate within 24 hours or the candidate does not arrive during the scheduled time, the exam fee will be forfeited. Cancellation notices will only be accepted from the candidate; employers, family members or other individuals may not request a cancellation on behalf of candidates. An exception to this rule may be made by an employer who originally registered the candidate with LaserGrade and directly paid the examination fee.

Cancellation by LaserGrade. LaserGrade Testing Centers may close without notice in the case of inclement weather, a state of emergency or other unforeseen event. In this case, the candidate will be allowed to reschedule at a convenient time and location with the exam fee credited to the future exam appointment. Candidates may verify that the LaserGrade Test Center is open by calling the center directly shortly before the appointed time.

6. Examination Rules of Conduct and Confidentiality

Passing the ExCPT is a big step in a pharmacy technician's career. Understandably, candidates will want to take advantage of all available resources when preparing for this important examination. It is *illegal and unethical to* recall (memorize) and share questions that are on the ExCPT or to solicit questions that are on the ExCPT from candidates who have taken the exam. ITEMS FROM THE EXAMINATION ARE NOT TO BE RECALLED FOR ANY PURPOSE.

Soliciting recalled questions from candidates who have previously taken the examination is unethical for several reasons. The first is obvious; candidates are expected to pass the test based on their own merit without assistance. The members of the public who will entrust certified technicians with their well-being expect that that they are trustworthy and competent individuals. Secondly, the purpose of the ExCPT is to protect the public by ensuring that candidates for licensure have achieved entry-level competence. By asking previous test takers to share questions, candidates are undermining the very purpose of the examination. Lastly, soliciting questions from previous test takers who have agreed to the Candidate Attestation would be encouraging candidates to commit illegal acts. ITEMS FROM THE EXAMINATION ARE NOT TO BE SOLICITED FOR ANY PURPOSE.

ICPT will actively prosecute individuals who violate the Attestation Agreement. The Institute will also report any incidents of students requesting questions or sharing questions to their licensing jurisdiction. Candidates who are prosecuted by ICPT or who are reported to a licensing jurisdiction for soliciting or sharing questions may severely damage their chances of achieving certification.

Before taking the ExCPT, Candidates must agree to comply with the following attestation:

Candidate Attestation

As a condition for taking the ExCPT, I certify that I have read, understand and agree with the following statements:

1. The ExCPT and its test items are the exclusive property of the Institute for the Certification of Pharmacy Technicians and are protected by copyright.
2. The ExCPT and its test items are valuable proprietary information and are understood to be confidential. The loss or outside disclosure of these materials or the information contained herein would harm ICPT economically and would subject the perpetrator to severe civil and criminal penalties as well as invalidation of certification
3. Candidates may not cheat or violate the confidentiality of the exam. Cheating or violation of confidentiality may be defined as, but not necessarily limited to the following:

    - obtaining help from any other person during an examination
    - communicating with or giving help to another candidate during and examination
    - using notes, books, or any other sources of information during an examination
    - using electronic programmable devices, such as calculators, cell phones, and PDAs during an examination
    - reproducing or making copies of the ExCPT or test items by any means
    - memorizing test items
    - discussing or disclosing the contents of the examination by any means
    - providing false or purposely misleading information when applying for or registering for the exam

4. I agree that any claim I may have related to the good-faith enforcement of these policies or the unintentional damage or loss of my exam records will not exceed the amount of my application fee for this examination.

Procedure for Handling Suspected Cheating Incidents. Candidates will be notified through a "Candidate Attestation" at the time they register and/or take the test that cheating will not be tolerated and that there will be appropriate penalties.

When cheating is detected, the LaserGrade Testing Center Specialist (TCS) will, in most circumstances, allow the candidate to finish taking the exam. However, the TCS will stop the exam if the candidate: (a) becomes unruly, (b) is interfering with other candidates, or (c) is copying questions on the exam. In all cases the TCS will secure the exam and a copy of the videotape and any other evidence.

The LaserGrade TCS will then write an incident report and send it to ICPT within 24 hours. The report will include the following information: date, time, location, proctor

name, candidate's name, candidate's Social Security Number, test version, a full description of the incident and a list of the evidence supporting the allegation.

LaserGrade will report the candidate's grade as "pending." Candidates will be notified that the ICPT investigation may take up to 30 days. If ICPT determines that the candidate violated the ICPT policies on cheating and confidentiality, it may seek a range of remedies depending upon the severity of the case, including but not limited to taking civil or criminal action against the candidate, suspending eligibility, and/or referring information about said misconduct to the respective board(s) of pharmacy Candidates will be given due process to appeal this decision before a member of the ICPT Board of Directors and two other qualified, unbiased individuals.

8. Taking the Exam

Identification required. In order to take the exam, candidates are required to present government-issued photo identification, such as a valid passport, driver's license, US Armed Forces photo identification or a non-driver's identification issued by a state department of motor vehicles. The identification must be clear and legible. The name on the photo identification must be the same as on the original registration. If the names are different then a certified or notarized copy of a marriage license, divorce decree, adoption papers or other legal documentation of name change. If the address on the government-issued photo identification is different from that supplied at the time of registration, the candidate must show proof of address, such as a current utility bill.

Prohibited items. Candidates may not bring any paper, books, cell phones, calculators, pagers, scanners, cameras or PDAs with them into the examining room. Candidates may be inspected for such materials prior to the exam. All purses, brief cases and other personal items will be securely locked up during the exam. The testing session may be videotaped for additional security.

Materials supplied. Candidates will be supplied with two blank sheets of paper and a pencil. The paper must be returned to the proctor at the end of the exam. A calculator will be available on the computer. Easy instructions on using this calculator and for navigating through the exam items and submitting the final answers will be given at the time of the exam. Candidates may also preview these instructions on the LaserGrade website at www.lasergrade.com.

Questions. No questions concerning the content of the examination may be asked during the testing period.

Comments. Candidates will be given the opportunity to comment on any question that they believe is ambiguous, inaccurate or deficient. A comment section for this purpose is provided at the end of the exam. All comments submitted will be reviewed by the ICPT Expert Panel. Responses are not provided to individual comments. Candidates will also be asked to complete a brief survey at the end of the exam to rate the exam registration procedures, the testing facility and general satisfaction with the testing experience.

9. Scoring Exams and Reporting Results

Exam results for successful candidates. The ExCPT is scored immediately and successful candidates are given an official report by LaserGrade indicating that they passed the ExCPT immediately after completing the exam. Candidates may use this report to provide evidence to employers or regulatory boards that they passed the ExCPT and are a certified pharmacy technician.

Exam results for unsuccessful candidates. The purpose of the exam is to provide summative assessment (i.e., to determine whether an individual has achieved a certain level of competency). It is not designed for formative assessment (i.e., to give the candidate feedback). ICPT does, however, provide diagnostic reports to help unsuccessful candidates focus their study time so they can successfully retake the exam. Candidates can also get some formative feedback by answering the practice problems that are offered on the ICPT website.

Candidates who do not pass the Exam will be allowed to retake the exam after four weeks. Since there are multiple versions of the Exam, candidates who take retake the Exam will receive a different, but equivalent, set of questions.
Passing score. The passing score is established by the ICPT Expert Panel based on a standard of performance that experts in the profession have determined are acceptable for this certification program. Specifically, the Expert Panel uses a modified Angoff procedure to determine the passing score. With this method each panelist independently estimates the percentage of qualified candidates who would correctly answer each item. The panelists' ratings are averaged to determine the passing score (also known as the "cut score"). The overall passing score is determined by averaging the individual ratings. The extreme high and low ratings can be deleted to decrease the variance without affecting the median score. The passing score is not based on a curve.
Recognition of certification. Pharmacy technicians who successfully pass the *ExCPT* are considered Certified Pharmacy Technicians and will receive a certificate suitable for framing.

Confidentiality of scores. Exam results for successful candidates will be available to state boards of pharmacy and, if authorized by the candidate, may be made available to employers as well. A list of Certified Pharmacy Technicians who passed the ExCPT will be available to the public. Unless authorized by the candidate, scores will not be released nor the identity revealed of candidates who do not pass the ExCPT.

Appeals and rescoring. Candidates who wish to appeal their test results or a specific test item will be allowed to do so by completing an appeal form and remitting a nominal examination review fee. The appeal form is available from the Director of Education and is used to record these requests and keep track of the reasons for the request as well as the results of the review. The Director of Education, with consultation from the Expert Panel if necessary, will respond to the candidate within ten working days.

Requests for duplicate certificates. Candidates who need a duplicate certificate may obtain one for a nominal charge by completing a request form available on the ICPT website. Individuals requesting a name change must provide notarized proof of the name change.

Reexamination. Candidates who do not pass the ExCPT will be allowed to retake the exam after four weeks. Since there are multiple versions of the ExCPT, candidates who take retake the exam will receive a different, but equivalent, set of questions.

10. Standards for Assuring Quality of the ExCPT

APA Standards. The ExCPT meets the standards of the American Educational Research Association, American Psychological Association and National Council on Measurement in Education, *Standards for Educational and Psychological Testing.*

NCCA Standards. The ExCPT follows the standards of the National Commission for Certifying Agencies (NCCA), the accreditation body of the National Organization for Competency Assessment. These standards for certification programs are considered to be more demanding than the APA standards. Our audit by an independent expert in psychometrics used these standards in her audit of the exam.

Development of exam. The above-referenced standards require that certain steps be followed to assure the psychometric soundness of a certification exam. These steps include the following:

- *Practice analysis.* A comprehensive job/practice analysis is conducted to clearly delineate performance domains and tasks and the associated knowledge and skill sets for pharmacy technicians. Among other things, respondents indicate the criticality and amount of time spent by technicians on various job tasks. Individuals are surveyed from a stratified sample of pharmacy technicians as well as technician supervisors and trainers from all practice settings. The sample size is large enough to give sufficient statistical power and to make proper inferences from the data and appropriate subsets of the data, New practice analyses are conducted on a periodic basis, usually every two years.

- *Exam blueprint.* The results of the practice analysis and input from stakeholders are used by the Expert Panel to determine the content areas to be tested on the exam and the weight given to each of these content areas. The result is the production of a document known as the exam blueprint, which will be available to all stakeholders. The ExCPT consists of 110 multiple-choice questions, including 10 pilot questions. Exam questions fall into three general areas: (1) Regulation and Technician Duties (~25%), (2) Drugs and Drug Products (~25%); and (3) The Dispensing Process (~50%).

- *Item writing.* A panel of volunteer item writers from a wide range of pharmacy practice settings are used to submit exam items. These item writers include

pharmacy college professors, pharmacists and certified pharmacy technicians who have strong expertise in specific pharmacy practice settings. All item writers are instructed on the standards for writing acceptable multiple-choice exam items. All items submitted are numbered, categorized according to topic and coded to identify the writer. All items are submitted to an extensive review process before being adopted as a part of the ExCPT exam test bank.

- *Expert panel review.* A panel of five to ten highly qualified individuals from a diverse set of practice settings are appointed to the Expert Panel to review all items submitted by item writers. The panel accepts those items that meet the standards and either amend or reject other items. All items accepted must first be pretested before being used in an exam. The Expert Panel also reviews results of the practice analysis, establishes the exam blueprint, sets the passing score and approves the equating and scaling procedures.

- *Pilot testing.* As with all standardized tests, the *ExCPT* contains some questions that are being pretested for possible use on future exams. Pretesting additional questions is necessary to assure that all items perform properly and that new versions of the Exam can be used in the future. The pretest items are interspersed throughout the exam and are not be identified for the candidate in order to assure that test statistics are valid.

- *Item analysis.* All items are submitted to an extensive process known as an item analysis. This item analysis consists of statistical procedures to determine the difficulty, discrimination, reliability and validity of all items before they are used as scored questions in the ExCPT. Item analyses are conducted on a regular basis, at least bimonthly.

- *Passing scores.* See the discussion in the previous section.

- *Equating and scaling.* To protect the integrity of the exam, multiple versions of the ExCPT are used. Candidates are randomly assigned to take one of the versions of the exam. If candidates need to retake the ExCPT, they are assigned to a different version of the exam. The various versions are carefully equated to assure that all offer the same challenge. Equating is essentially a statistical method of selecting the raw score on each test that would provide the same probability of passing. In other words, it is a way of calibrating different versions of the exam to assure that they provide an equal challenge. For example, a raw score of 75 may be determined to be a passing score on one version of the exam and a 74 may be determined by the Expert Panel to be the equivalent passing score on a more difficult version.

  To assure consistency among various versions of the exam, scores are converted to a scaled score instead of a raw score. A scale is a score-reporting technique that translates the different raw scores into a standard score. For example, the scores that may be earned on the ExCPT range from 200 to 500 and the passing

score is 390. The minimum passing raw scores are then converted to 390 for all versions of the exam. If two different versions of the exam have different cut scores (e.g., a raw score of 75 on one version and a raw score of 74 on another) then both are converted so that 390 is the passing score. Reporting only raw scores could cause confusion because the results of one test administration may be difficult to compare with another that does not have exactly the same difficulty or same cut score. Equating and scaling procedures are used in most certification programs because they are easy and reliable, commonly accepted as standard procedures in certification programs, psychometrically sound and are legally defensible.

- *Rotating and retiring test items.* The integrity of the exam is further protected by rotating and retiring test items on a regular basis. Candidates who have to retake the exam several times would not see the same exam again because they would be assigned to all of the different versions before they could retake the same version. During the time before retaking the same version, most of the questions would have changed. All versions of the exam, however, will be consistent with the exam blueprint and will be equated. In addition to rotating and retiring test items, the order of test items and answers are scrambled and numbers for calculation questions are changed on a frequent basis. Questions that are retired from the exam can be used later as practice questions.

- *Independent audit by expert in psychometrics.* An independent, unbiased expert in psychometrics is retained to audit the ExCPT procedures, content and exam items. An audit of the exam developed for the Virginia Board of Pharmacy follows all ExCPT test procedures and was audited by Dr. Dana Hammer of the University of Washington in February 2004. A more recent audit of the ExCPT content and procedures was conducted by Dr. Hammer in February 2006. Dr. Hammer used the certification standards and guidelines established by the National Commission for Certifying Agencies. Dr. Hammer's opinion was that the exam meets the standards for certification programs and is psychometrically sound. It is the intent of ICPT to continue conducting independent audits of the ExCPT.

11. Services to Boards of Pharmacy

Reporting and maintaining results. Exam results are posted on a secure website designed specifically for board of pharmacy use. With a password, authorized board of pharmacy staff members may check ExCPT records to determine whether specified pharmacy technicians are certified by ExCPT. ExCPT records can also be used to update board records and to generate reports from the certification database. An online users manual is provided to help boards of pharacy to make optimal use of the website.

Reciprocity. Boards of pharmacy can use the secure website to verify certification the current status of all ExCPT-certified pharmacy technicians for purposes of reciprocity.

Boards can also be notified of any pharmacy technicians whose certification has been revoked.

12. Revocation

ICPT may revoke the certification of a pharmacy technician for any of the following reasons:

- Submission of false or misleading information in connection with certification or recertification;
- Violation of any of ICPT's policies on exam cheating or exam confidentiality or failure to cooperate with ICPT in the investigation of any such incident by another candidate.
- Conviction of a felony or a crime involving prescription medications or controlled substances (including but not limited to the illegal use, sale or distribution of prescription medications or controlled substances);
- Revocation or suspension of a pharmacy technician registration or license by a state board of pharmacy;
- Documentation of gross misconduct or gross negligence of duties to a state board of pharmacy.

13. Recertification

Application. The first ExCPT Certified Pharmacy Technicians were issued certificates in October, 2005. Since certification expires after two years, these individuals will be the first to recertify starting in October 2007. During the two-year period prior to recertification, certified pharmacy technicians must participate in at least 20 hours of continuing education (CE), including at least one hour of pharmacy law. To recertify, technicians must use the ICPT recertification application form and may file either online or by regular mail. Complete instructions will be provided with the form. Address changes should be sent to the Institute so that we may send a recertification application approximately 60 days prior to the expiration date. Technicians will be allowed to recertify up to 90 days after expiration of their certification but cannot include CE credit earned during this grace period. After this 90-day period, there will be a late fee.
Continuing education. To be approved, CE credit must be related to pharmacy technician practice. Acceptable topics include, but are not limited to: drug distribution, inventory control, managed health care, drug products, therapeutic issues, patient interaction, communication and interpersonal skills, pharmacy operations, prescription compounding, calculations, pharmacy law, preparation of sterile products and drug repackaging.

Certificates of participation must be obtained for each CE program. This certificate must include the name of the participant, the title of the program, date of the program, number of contact hours, the name of the sponsor and the signature of a person responsible for the program.

CE programs offered by national and state pharmacy associations and pharmacy technician associations will generally be acceptable if related to pharmacy technician practice. Applicable college courses with a grade of "C" or better will also be eligible for CE credit at the rate of 15 CE hours for each a 3credit-hour course offered on a semester basis (i.e., three hours a week for 15 weeks). Courses offered on a quarter basis will be credited for 15 hours for a 4 credit-hour course (i.e, four hours per week for approximately 11 weeks). The maximum number of CE credits earned through college courses during a two-year period is 15. Recertification may be conducted on-line or by mail beginning in October 2007.

Appendix 2

ExCPT Practice Analysis
List of Pharmacy Technicians Practice Functions

Question	Mean Importance	Relative Frequency	Relative Time
Understand the necessity of having a pharmacist check all work performed by the technician.	4.91	1.00	1.00
Use proper procedures to avoid prescription errors.	4.88	1.00	1.00
Use proper procedure to assure delivery of the correct prescriptions to patients.	4.83	1.00	1.00
Properly count, measure or compound the drug to be dispensed.	4.82	0.98	0.98
Accurately enter prescription information and drug history into the computer.	4.82	1.00	1.00
Demonstrate a clear knowledge of the line between tasks that may be performed by a pharmacy technician and those that must be performed by pharmacist.	4.82	1.00	1.00
Use correct procedures in preparing prescriptions for dispensing.	4.80	1.00	0.98
Describe the functions that a pharmacy technician cannot perform	4.80	0.75	0.72
Properly process third-party prescriptions.	4.79	0.56	0.49
Maintain HIPAA compliance while communicating with patients.	4.74	0.97	0.80
Correctly translate a prescriber's directions for use into accurate and complete directions for the patient.	4.74	0.99	0.99
Follow the proper rules and regulations when filling prescriptions.	4.73	1.00	0.83
Use the proper DAW code when entering prescription data.	4.72	0.52	0.52
Prepare prescription labels or patient information.	4.72	1.00	1.00
Correctly calculate prescription quanties and days supply.	4.69	0.83	0.87
Properly label drug products packaged in approved containers or, when appropriate, in original containers.	4.67	0.99	0.99
Properly package the drug to be dispensed in child-resistant containers or other approved containers as required.	4.67	0.99	0.99
Take proper action when a compliance alert is noted when entering a prescription.	4.65	0.80	0.81

Demonstrate knowledge of abbreviations used on prescriptions and familiarity with the ways in which abbreviations can be misinterpreted.	4.64	0.99	0.99
Communicate accurately and appropriately with patients.	4.62	1.00	0.98
Follow the proper rules and regulations when handling refills, partial filling and transfers of controlled substances among pharmacies.	4.53	1.00	0.90
Properly repackage drug products and label correctly and, in the case of repackaged medications, include the correct expiration date.	4.47	0.91	0.86
Identify which reject codes returned by third-party processors can be handled by a technician.	4.45	0.48	0.46
Properly file prescriptions	4.41	0.97	0.97
Demonstrate awareness of the compliance/interaction checks that a pharmacy computer performs.	4.38	0.90	0.83
Describe what information is required on completed prescription forms and how to gather any information that is missing.	4.35	0.93	0.93
Assist with inventory control and maintenance.	4.31	0.70	0.59
Follow the correct procedures for handling patient requests for pseudoephedrine.	4.31	0.27	0.19
Describe the purpose of patient profiles and how to enter, update, and maintain them.	4.26	0.78	0.76
Explain HIPPA requirements to patients (e.g., why they have to sign for prescriptions when picked up).	4.26	0.47	0.19
Identify the therapeutic class for commonly used durgs (e.g., analgesic, antibiotic, etc.)	4.21	0.68	0.62
Describe the difference between prescription and OTC medications and describe major theraputic classes of the latter	4.20	0.79	0.65
Describe strategies for avoiding mix-ups among easily confused products.	4.19	0.11	0.15
Identify and interpret the various methods used to indicate the quantity of medications to dispense.	4.17	0.87	0.85
Properly stock automated dispensing devices or other devices used in the dispensing process.	4.16	0.55	0.29
Assist in proper inventory maintenance.	4.15	0.90	0.89
Demonstrate knowledge of federal and state laws and regulations affecting pharmacy.	4.15	0.65	0.29
Use aseptic technique to prepare parenteral medications	4.15	0.30	0.27

Accept refill authorizations from prescribers or their authorized agents, provided there is no change to the original prescription.	4.15	0.78	0.19
Describe the different types of information conveyed on prescription labels and receipts.	4.13	1.00	1.00
Identify the brand and generic names of the most commonly used prescription drugs.	4.13	0.89	0.92
Compound intravenous medications and TPN	4.10	0.35	0.38
Understand proper use of auxiliary labels.	4.09	0.76	0.72
Help maintain the security of the pharmacy department	4.09	0.90	0.81
Demonstrate knowledge of terms and units of measurement in each of the systems of measurements and the ability to convert from one system to another.	4.08	0.72	0.74
Properly handle real or perceived medication errors.	4.07	0.87	0.83
Follow the correct procedures for handling Schedule V sales without a prescription.	4.05	0.42	0.21
Compound liquid, solid and semi-solid dosage forms	4.03	0.40	0.18
Demonstrate knowledge of record-keeping requirements.	4.02	0.99	0.97
Understand laws and regulations regarding generic substitution	4.00	0.80	0.51
Cite rules and regulations regarding time limits for refilling prescriptions.	3.99	0.94	0.92
Cite information required on completed prescription forms.	3.99	0.89	0.82
Assure maintenance of adequate supplies of prescription vials, caps, bottles, and other supplies.	3.89	0.96	0.77
Explain what generic drugs are and how they compare to brand-name medications.	3.85	0.40	0.27
Describe the state law regarding the substitution of generic equivalents.	3.78	0.52	0.22
Answer patients' questions about prescription coverage under the Medicare Modernization Act.	3.75	0.68	0.49
Differentiate among the controlled substances schedules.	3.56	0.96	0.32
Identify the types of information found on medication stock bottles.	3.53	0.77	0.17
Identify the most common indication for the most commonly used prescription drugs.	3.40	0.96	0.93
Demonstrate familiarity with the characteristics of and cite examples from each of the four major categories of dosage forms.	3.32	0.15	0.15

Demonstrate a working knowledge of different types of drug dispensing systems (e.g., multidose vials, punch cards, and unit-dose packaging.)	3.27	0.68	0.47
List the practitioners who are authorized to prescribe medications.	3.21	0.23	0.17
Recognize common and severe adverse drug reactions, contraindications and drug interactions.	3.09	0.20	0.19
Understand the role of federal agencies such as FDA and DEA	3.00	0.25	0.02
Explain the role of the state board of pharmacy.	2.87	0.04	0.04
Describe the mechanism of action of various drug classes	2.23	0.04	0.04

Appendix 3

Exam for the Certification of Pharmacy Technicians

Exam Content (v1.4)

(valid through Sept. 30, 2006)

1. Regulations and Technician Duties (~25% of exam)

Overview of technician duties and general information

- The role of pharmacists and pharmacy technicians
- Functions that a technician may and may not perform
- Prescription department layout and workflow
- Pharmacy security
- Role of government agencies (Board of Pharmacy, DEA, FDA, etc.)
- Inventory control
- Stocking medications
- Identifying expired products

Controlled substances

- Difference among the controlled substances schedules
- Laws governing refills, partial refills, filing, and transfers of controlled substances
- Correct procedures for handling Schedule V sales

Other laws and regulations

- Federal privacy act (operational procedures, communications, incidental disclosures and patient rights)
- Laws and regulations regarding generic substitution (incl. differences between brand and generic products)
- Professionals with prescribing authority (and acronyms)

2. Drugs and drug products (~25% of exam)

Drug Classification

- Major drug classes (e.g., analgesics, anesthetics, antibiotics, antiseptics, etc.)
- Basic mechanism of action and indications
- Dosage forms (types, characteristics and uses)

Most frequently prescribed medications

- Brand and generic names
- Drug class
- Primary indications
- NDC number
- Avoiding dispensing errors (e.g., sound-alike and look-alike drug names)
- Common adverse drug reactions, drug interactions, contraindications and side effects

3. Dispensing Process (~50% of exam)

Preparing prescriptions

- Information required on a valid prescription form
- Telephoned and faxed prescriptions
- Refill requirements
- Patient information (age, gender, etc.)
- Interpreting prescribers' directions for prescription labels
- Recognizing and using common prescription and medical abbreviations

Dispensing prescriptions

- Avoiding errors (e.g., sound-alike/look-alike names, other common errors)
- Systems for checking prescriptions
- Automated dispensing systems (including quality control)
- Correct procedures to prepare prescriptions and enter information in the computer
- Labeling prescriptions properly
- The purpose and use of patient records
- Proper packaging and storage
- Child-resistant containers
- Managed care prescriptions (submitting claims, reimbursement, reconciliation, partial fills, chargebacks and verifying delivery to the patient)

Calculations

- Systems of measurement used in pharmacy
- Calculating the amounts of prescription ingredients
- Calculating quantity or days supply to be dispensed

- Calculations use in compounding (e.g., ratio strength, w/w%, w/v, v/v, dilution/concentration, mEq, etc.)
- Calculating administration rates for IVs

Sterile products, unit dose and repackaging

- Drug distribution systems used in hospitals and nursing homes (e.g., unit dose)
- Procedures for repackaging medications
- Prescription compliance aids
- Aseptic technique and the use of laminar flow hoods
- Special procedures for chemotherapy
- Routes of administration for parenteral products
- Types of sterile products
- Correct procedures for maintaining the sterile product environment
- Accurate compounding and labeling of sterile product prescriptions
- Calculation of dosages and administration rates

Appendix 4

Exam for the Certification of Pharmacy Technicians

Partial List of Item Writers and

Their Respective Areas of Expertise

Name	Location	Expertise
Kelly Burch, Pharm.D.	St. Louis, MO	Hospital practice and home health care
Manisha Chander, Pharm.D.	Morton Grove, IL	IV infusion and home health care
Rasma Chereson, R.Ph., Ph.D.	St. Louis, MO	Community practice, compounding, parenteral therapy kinetics and pharmaceutics
Laura Cranston, R.Ph.	Fairfax Station, VA	Community practice
Eric Hobson, Ph.D.	Savannah, GA	Patient interaction and communication, pharmacy education
Douglas Hoey, R.Ph.	Alexandria, VA	Community practice
Delphine Knop, Pharm.D.	Des Plaines, IL	Hospital practice
Tejal Pandya, Pharm.D.	Schaumburg, IL	Long-term care
Dan Pepe, PhD,	San Antonio, TX	Hospital practice
Donald Rickert, R.Ph., Ph.D.	Belleville, IL	Hospital practice, pharmacy law
Elizabeth S. Russell, R.Ph.	Richmond, VA	Pharmacy law
Kenneth W. Schafermeyer, R.Ph., Ph.D.	University City, MO	Community practice, pharmacy education
Walter Thomas Smith, Pharm.D., J.D.	St. Louis, MO	Home health care, compounding, calculations and law
Peggy Summers, R.Ph.	Lake Jackson, TX	Community and hospital
Tasha Williams, Pharm.D.	Chicago, IL	Community pharmacy

Brandon Williams, Pharmacy Technician	Collinsville, IL	Community pharmacy
Dan Yee, Pharm.D.	Orlando FL,	Hospital, medical writer, clinical coordinator
New members to be added:		
Anita Benavidez, CPhT	Phoenix, AZ	Hospital and pharmacy benefit management
Ray Tanaka, R.Ph.	Elmhurst, IL	Health system pharmacy and nuclear pharmacy

Appendix 5

Letters of Reference for Independent Expert in Psychometrics, Dr. Dana Hammer, who audited the ExCPT

1. Dr. Eric Hobson, Associate Dean, South University College of Pharmacy

2. Dr. Robert McCarthy, Dean, University of Connecticut College of Pharmacy

SouthUniversity℠

School of Pharmacy
709 Mall Boulevard
Savannah, GA 31406-4881
(912) 201-8120

Members of the Connecticut Commission of Pharmacy
c/o William J. Summa, Jr., Chairman
Department of Consumer Protection
Commission of Pharmacy
165 Capitol Ave.
Hartford, CT 06106

25 March 2006

Members of the Connecticut Commission of Pharmacy & William J. Summa, Jr., Chairman:

At the request of Kenneth Schafermeyer, Ph.D., and the Institute for the Certification of Pharmacy Technicians, I offer the following assessment of the appropriateness of the use of Dana P. Hammer, Ph.D. to carry out a detailed audit of the Virginia Pharmacy Technician Exam (audit report filed in February 2005). As part of this assessment, I have reviewed the following: Dr. Hammer's February 2005 audit report, Dr. Hammer's CV, NCCA Standards and Essential Elements. Additionally, I bring to this assessment 15 years experience in pharmacy education, expertise in outcomes definition and assessment, psychometrics, test design and administration, awareness of the pharmacy education community's confidence in Dr. Hammer's work, and my respect for Dr. Hammer's accomplishments.

My review of these materials leads me to concur with Dr. Hammer's assessment that the Virginia Pharmacy Technician Exam is psychometrically sound and offers a reliable tool for ascertaining the performance capabilities of individuals who sit this examination.

Assessments offered by Dr. Hammer are impeccable. Her work is consistently sound, accurate, and conforms to the highest standards of practice. Invariably, Dr. Hammer's work sets standards for others to emulate. Her audit of the Virginia Pharmacy Technician Exam addresses every question that I would have asked had I carried out a review of the exam in question. Likewise, the analyses she used are appropriate and allow for a fine-grained analysis of macro- and micro-level issues related to construct validity, consistency across offerings, item strength and higher-order outcomes assessment. This audit is a fine piece of work.

Dr. Dana P. Hammer is uniquely qualified to carry out a detailed assessment of evaluation tools used to determine pharmacy-related knowledge, skill, and attitudinal competence. Her graduate-level training is unique: she completed the Doctor of Philosophy degree option in pharmacy offered at Purdue University, the only program of its type designed to provide pharmacy with highly-trained educators. This doctoral program requires extensive coursework linked to research-based practice activities that ensure that individuals in this program have mastered such topics as research design, educational assessment theory and methods, analytical methodology in clinical and educational practice, and high-stakes testing.

The pharmacy education community recognizes Dr. Hammer's expertise and capability. She is called upon routinely to consult with the development of educational curricula in didactic and practice situations. She serves as a regular faculty member at the American Association of Colleges of Pharmacy Summer Institutes on Curricular Design and Assessment, staffs the intensive program for new faculty and preceptors offered by the American College of Clinical Pharmacy, and is leading nation-wide efforts to develop systematic approaches to pharmacy preceptor training.

Dr. Hammer's high standing in the pharmacy education community is further supported by the fact that, to date, she has twice been awarded the Rufus Lyman Award for significant contribution to the pharmacy education literature. Few pharmacy educators have been thus recognized. I expect that she will receive this award more than once again based upon the strength of her assessment-focused research projects that are currently underway or in the planning stages. My appreciation of Dr. Hammer's skills runs deep: she is one of two or three professional peers to whom I turn when I need to better understand complex educational issues, discuss assessment methodology, or get a trusted peer review of assessment tools or research design protocols.

Should you or your colleagues require further comment about this particular issue, please feel free to contact me. Email is the most convenient method and can allow us to arrange a time to talk in detail.

Collegially yours,

Eric H. Hobson, Ph.D.
Associate Dean for Academic Affairs and Assessment
Professor of Pharmacy Practice
(912) 201-8125
ehobson@southuniversity.edu

University of Connecticut
School of Pharmacy

March 24, 2006

William Summa, R.Ph.
President
Connecticut Pharmacy Commission
Hartford

Dear Billy:

I wanted to drop a short note to you and your fellow Commission members regarding two of my long-time colleagues, Drs. Kenneth Schafermeyer and Dana Hammer. I know that Dr. Schafermeyer will be appearing before you next week regarding an alternative pharmacy technician exam; Dr. Hammer, as I understand it, conducted an audit of the exam.

Both Drs. Schafermeyer and Hammer are highly regarded by their faculty peers around the country and particularly by those of us within the social and administrative sciences discipline. The quality of their research is superb and their perspective is valued by those of us in the academy. Equally important, they are known as individuals of high integrity. I can assure you that they are honest, forthright, and not known for hyperbole. Though one may disagree with their perspective, you can be assured that their conclusions have followed careful analysis and study.

It's not appropriate for me to offer an opinion of the proposed alternate test; I have not studied it sufficiently to do so. I ask only that you listen to Dr. Schafermeyer's presentation with an open mind, confident that he will present a qualified, honest assessment of the alternate test.

Many thanks,

Robert L. McCarthy, Ph.D.
Dean and Professor

Appendix 6

Exam for the Certification of Pharmacy Technicians

Expert Panel Members (05/2006)

Name	Position	Location	Practice Experience	Other Expertise
Anita V. Benavidez, BS, CPhT	• Former Analyst, United Health Group • Former instructor, Midwestern University College of Pharmacy	Phoenix, Arizona	• Hospital Pharmacy Technician • Pharmacy Education • Managed Care	• PTCB-Certified Pharmacy Technician • PCCA compounding and aseptic technique certificates • Pharmacy benefit management
Bette Cataldo, Pharm.D.	• Clinical Pharmacist, Missouri Baptist Hospital (ret.) • Assistant Pharmacy Director, St. Louis University Hospital (ret.)	St. Louis, Missouri	• Hospital Pharmacy • Home Health Care • Technician Training	• Pharmacy compounding • Home IV preparation
Rasma Chereson, R.Ph., Ph.D.	• Professor of Pharmaceutics, St. Louis College of Pharmacy • Community pharmacy practitioner, Medicine Shoppe International	University City, Missouri	• Pharmacy Education • Community Pharmacy	• Teacher of : > Pharmacokinetics > Pharmacy Compounding > Parenteral Therapy > Pharmacy Dispensing

Dana P. Hammer, R.Ph., Ph.D.	• Psychometrician and Director of the Bracken Pharmaceutical Care Learning Center, University of Washington College of Pharmacy	Seattle, Washington	• Pharmacy Education • Community Pharmacy • Hospital Pharmacy	• Expert psychometrician. • Teacher of: > Advanced Compounding Skills > Educational Design > Pharmacy Practice Laboratory
Timothy R. Koch, R.Ph.	• Government Relations Manager, Wal-Mart Pharmacies • Former Vice President, MO Board of Pharmacy	Bentonville, Arkansas	• Hospital Pharmacy • Community Pharmacy • Board of Pharmacy	• Pharmacy laws and regulations
Justin Lusk	• Pharmacy technician and 2nd Lt. USAF	Jackson, Missouri	• Community Pharmacy (technician)	
Merry Lynn Schmittgens, R.Ph.	• Owner, Medicine Shoppe Pharmacy • Instructor of Pharmacy, St. Louis College of Pharmacy	Affton, Missouri	• Hospital Pharmacy • Community Pharmacy • Pharmacy Education	• Pharmacy compounding
Mayur Shah, Pharm.D.	• Owner, MRxI, Inc. • Owner, Broadway Avenue Pharmacy	Chicago, Illinois	• Hospital Pharmacy • Community Pharmacy • Pharmacy Benefit Management	• Oncology/hematology specialist • Pain management specialist • Chemotherapy compounding
Walter Thomas Smith, Pharm.D., J.D.	• Assistant Professor of Pharmaceutical Sciences, St. Louis College of Pharmacy	St. Louis, Missouri	• Home Health Care / Long-Term Care • Pharmacy Education	• Teacher of: > Introduction to Pharmacy Practice > Pharmacy Calculations. > Biomedical Ethics • Sterile product compounding • Pharmacy law

Note: This Expert Panel represents a diverse range of pharmacy practice settings, experiences and locations. Members have practice experience from all over the United States including: Alaska, Arizona, Arkansas, Colorado, Illinois, Indiana, Kansas, Massachusetts, Michigan, Missouri, Nebraska, Oregon, Tennessee, Texas, Virginia, and Washington.

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Appendix 7

LaserGrade Test Center Requirements

1. GENERAL

A. Testing Center must conform with local building, sanitation, and health codes.
B. Building and grounds must be clean and in good condition.
C. The exits must be clearly marked and unobstructed.
D. Fire extinguishers, when required, must be in working order, the location well marked, and easily accessible.
E. Emergency exits must be clearly identified and clear of obstructions.
F. Emergency first-aid kits, if required, must be stocked and easily accessible.
G. Restrooms must be clean, supplied with towels, etc., and in working order.
H. Restrooms must be located in the same building as the testing center.
I. Adequate parking must be available, near the testing center location.

2. TEST ROOM ENVIRONMENT

A. Temperature must be consistent and comfortable.
B. Testing room must be well-ventilated, with continuous air circulation.
C. Testing room must be lit so that the candidate at each terminal can read all diagrams, charts, etc., and read the computer screen without difficulty.

3. TEST ROOM PHYSICAL SPACE

A. Testing room must be large enough to comfortably place the testing station(s), computer tables, chairs, and printer stand. Generally speaking, 120 square feet or larger is adequate.
B. Each testing terminal must be separated with a suitable partition or spaced five feet apart.
C. There must be enough table space for the computer monitor, keyboard, mouse pad and testing materials the candidate will be issued. A recommended table size is 42" X 30".

4. TESTING ATMOSPHERE

A. Testing area should be located so candidates will not be disturbed by foot traffic, loud conversation or outside noise.
B. Testing rooms shall be free from any other activity during testing sessions; during non-testing times, the testing room may be available for other uses.
C. In general, the testing center should provide a pleasant and comfortable atmosphere and be conducive to a good testing environment.

5. SECURITY and SUPERVISION

A. Testing must take place in a separate room with a closeable door.
B. Testing room must have a window, video surveillance system, or seating for an in-room proctor for test supervision. All must allow an unobstructed view of each candidate within the testing room.
C. Testing room door must be lockable. Access to this room must be strictly monitored. Only authorized personnel are permitted.
D. All testing materials must be secured when not in use. A locking file cabinet may be used for this purpose.
E. The testing room may be used for other purposes when not being used for testing.

6. REQUIRED EQUIPMENT and SUPPLIES

A. Copy machine or scanner to provide copies of candidate IDs and test eligibility for testing center files.
B. Facsimile machine allowing receipt of transmitted documents 24 hours per day.
C. A locking file cabinet to secure test materials and to store candidate files.
D. A printer stand for the testing center printer.
E. Clipboards for keeping candidate papers together before filing.
F. Three ring binders to organize testing material.
G. A spare printer cartridge.
H. A ream of scratch paper for the candidates. (Two sheets to each candidate)
I. Supply of #2 pencils. (Two are issued to each candidate)
J. Test report embosser, if required. (Supplied by LaserGrade)
K. Test supplement books, if required. These books contain graphs, charts and diagrams used in the computer test.
L. Pre-printed test report forms. (Supplied by LaserGrade)
M. Testing center procedures manual. (Supplied by LaserGrade)

LaserGrade Computer Specifications			
	LaserGrade Engine	MOS Engine	APTC Engine

	MHz At least 256 MB RAM Must have a CD-ROM	MHz At least 256 MB RAM	RAM
Operating System	Windows 98 or higher, networked or stand-alone.	Windows 98/2000	Windows NT or Novell network, or Windows 98/2000 stand alone or peer to peer
Network	Optional. We support NT and peer to peer. No wireless networks.	Simple LAN, peer to peer	Windows 2000 Pro optional
Telecom	Internet - DSL or higher	Optional, only necessary if needed for internet connection	External 56 Kbps modem
Printer	100% compatible with HP series of Inkjet or Laser printers.	300 DPI printer with Windows 95/98 support – must be installed as a DEFAULT printer on ALL MOS Workstations	Administrator and testing workstations must have access to an inkjet/laseror bubblejet printer with at least 600 DPI capabilities
Hard Drive	Minimum 5 Gig available space	250 MB available after installing Office 97	2 GB
Video	17" SVGA .28 pitch, displaying 256 colors on a 1024x768	Color VGA video display set to 640x480 resolution	SVGA color monitor and video card with 1 MB RAM and capable of 256 colors

	screen. Video card compatible with Trident 9440 with 2 Mb RAM, displaying 256 colors in both 1024x768 & 640x480		
Pointing Device	Microsoft or compatible mouse	Microsoft or compatible mouse	Microsoft or compatible mouse
Internet Access	All testing stations must have internet access.	Internet access via dial-up, network, or proxy server	Optional
Installed Applications	Internet Explorer 5.0 or higher. Adobe Acrobat Reader	Microsoft Office 2000 or XP Professional Edition– full installation	None required.

State of California | Department of Consumer Affairs

Memorandum

To: Licensing Committee | **Date:** Sept. 7, 2006

From: Board of Pharmacy – Virginia Herold

Subject: Emergency Preparedness for California

One of the Governor's key initiatives is emergency preparedness. Currently within the Department of Health Services is the Emergency Preparedness Office, which has been formed to coordinate state government's planning for emergencies.

In recent months, the board has received inquiries from this office and from county disaster response teams seeking information about what drug storage and distribution laws would be in place in emergencies that would facilitate drug distribution to patients and medical caregivers, perhaps in makeshift facilities.

Current California law, Business and Professions Code section 4062, provides the board with broad waiver authority:

> **4062.** (a) Notwithstanding Section 4059 or any other provision of law, a pharmacist may, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency, to further the health and safety of the public. A record containing the date, name, and address of the person to whom the drug or device is furnished, and the name, strength, and quantity of the drug or device furnished shall be maintained. The pharmacist shall communicate this information to the patient's attending physician as soon as possible. Notwithstanding Section 4060 or any other provision of law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.
> (b) During a declared federal, state, or local emergency, the board may waive application of any provisions of this chapter or the regulations adopted pursuant to it if, in the board's opinion, the waiver will aid in the protection of public health or the provision of patient care.

Also, a section of law dealing with refills could also aid pharmacists in providing medication to patients in an emergency:

> **4064.** (a) A prescription for a dangerous drug or dangerous device may be refilled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being.
> (b) The pharmacist shall inform the patient that the prescription was refilled pursuant to this section.
> (c) The pharmacist shall inform the prescriber within a reasonable period of time of any refills dispensed pursuant to this section.

(d) Prior to refilling a prescription pursuant to this section, the pharmacist shall make every reasonable effort to contact the prescriber. The pharmacist shall make an appropriate record, including the basis for proceeding under this section.
(e) The prescriber shall not incur any liability as the result of a refilling of a prescription pursuant to this section.
(f) Notwithstanding Section 4060 or any other law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

At this meeting, staff from the Department of Health Services will appear to begin a discussion with the board of how the board can assist its licensees in preparing to respond to disasters. The outcome of these discussions may involve legislative proposals and a special *Health Notes.*

During this first meeting, the DHS will provide information on:

- CDC's Strategic National Stockpile of drugs which can be provided quickly to disaster areas.
- The mission and vision of DHS and the Emergency Pharmaceutical Service Unit.
- "Points of Dispensing" (POD's) and the implications of mass prophylaxis and immunization. The Cities Readiness Initiative (CRI) is the worst case scenario where delivery of prophylaxis within 48 hours large populations exposed to anthrax with antibiotics.

The DHS indicates that it wants to ensure the board is aware of their plans so that concerns can be addressed at the front end, and licensees and the public will have better knowledge of what the board will require, and be willing and comfortable volunteering to participate in emergency response.

This committee is well-appointed to undertake this task. Chairperson Conroy was recently appointed to the National Association of Boards of Pharmacy Task Force on Emergency Preparedness, Response and the US Drug Distribution System. Board Member Susan Ravnan is on a county emergency response team.

I am also attaching a recent summary from the NABP newsletter regarding the disaster response of pharmacy boards in Louisiana and Mississippi following Katrina.

102nd Annual Meeting CE Session Provides Disaster Planning Pointers to Boards

There has been a lot of talk in recent years about government emergency preparedness and disaster planning, talk that became all the more frequent and earnest after 9/11. And yet, when Hurricane Katrina slammed into the Gulf Coast last summer, the whole country witnessed a graphic demonstration of what we were prepared for – and what we were not.

Katrina proved a wake-up call for the public and private sectors alike. Since then, officials in business and government have sought to take the lessons gained from Katrina and apply them, so that the next widespread disaster, whatever it may be and whenever it may occur, will not be met unprepared.

Lessons learned from Katrina and the steps the boards of pharmacy can and should take to prepare themselves to handle emergencies was the topic of the two-part seminar, "Structuring an Effective Disaster Plan: Lessons Learned" at NABP's 102nd Annual Meeting in April 2006 in San Francisco, CA. During the seminar, which involved both presentations and a panel discussion, the speakers shared their own experiences in the aftermath of Katrina, noted what did and did not work during the crisis, what they think should be improved upon for next time, what to expect from the federal government in terms of response and assistance, and steps the boards should take in the vital task of developing their own disaster plans. The first half of the session was co-presented by Malcolm J. Broussard, executive director of the Louisiana Board of Pharmacy and a member of the NABP Executive Committee, and Robert J. "Bob" Dufour, a member of the Arkansas State Board of Pharmacy and pharmacy director, professional services, for Wal-Mart Stores, Inc.

What Happened

In the aftermath of Katrina, Dufour offered his services to the Louisiana Board of Pharmacy, which was asked to take on a whole new role from its usual one. "The number-one goal at the Louisiana Board of Pharmacy is to affect the public safety," he said. "This is usually done through regulations and enforcing those regulations. In this case, the Louisiana Board was asked to do something different. The governor and the Office of Emergency Preparedness . . . had their hands full . . . . They asked the Louisiana Board, 'Would you take care of the medication needs for the state of Louisiana?'"

The first thing the Lousiana Board had done, of course, was to coordinate with state officials and the federal disaster response team to assess the situation and set up a triage area. Within a couple of days of the levee breaches, the state's Department of Public Health's pharmacy department (responsible for disaster response, but hampered by the inoperability of its office in downtown New Orleans) opened an emergency operations center in Baton Rouge, eventually working out of the Board office itself. Immediate tasks included ramping up the communications systems, coordinating volunteer pharmacist staffing coverage, and establishing a medication distribution system for operating shelters.

In assessing the situation in the immediate hours and days after Katrina hit,

with much information still sketchy, the Board realized that thousands of people – those who had been evacuated to shelters, those who had evacuated in a hurry under their own power, and even emergency response personnel – would not have their medications, nor would they be able to call their physician or their pharmacist to fill or refill prescriptions. "It was very clear," said Dufour, "there was a need for pharmacists to dispense emergency meds without a prescription."

And they did. In Louisiana, they were greatly aided by one section of regulations that had been on the books since 2004, said Broussard. This section "is triggered by the proclamation of a state of emergency by the governor," said Broussard. "There are two provisions of that. The first is the ability of licensed pharmacists from other states to come assist us in our state but who may not possess a Louisiana license. The rule states that during a state of emergency, if a pharmacist carries an active, current license from another jurisdiction, they may practice in our state for the duration of the declaration of the state of emergency." The second provision, meanwhile, allows a pharmacist in the affected area – "using sound, professional judgment" – to create and write a prescription for any medication and dispense up to a 30-day supply.

Speaker Richard A. "Rich" Palombo, an NABP Executive Committee member, recent member of the New Jersey Board of Pharmacy, and director of compliance, professional practice, for Medco Health Solutions of Franklin Lakes LLC, who joined in for the second half of the session, expressed his opinion that the latitude granted by these emergency measures contributed greatly to the caliber of patient care that pharmacists delivered under tremendously difficult circumstances. "We can have established rules that need to be in place all the time, but in these kinds of disasters . . . having the opportunity and the little bit of flexibility that the Louisiana Board afforded us allowed for much better patient care," he said. "In the magnitude of that kind of disaster, you've really got to rely on professional judgment and you have to rely on the distinction that pharmacists are very well trained and they will work for the benefit of the patients."

The importance of communication and coordination cannot be overstated. In order to provide needed medications to Katrina's victims, affected boards of pharmacy had to coordinate with numerous federal, state, and local agencies that were providing various aspects of relief and assistance to the medication effort, as well as agencies such as Food and Drug Administration, Drug Enforcement Administration, and United States Pharmacopeia; private sector entities – wholesalers that had the stock and knew the state's back roads, chain and independent pharmacies that "adopted" shelters and moved in personnel and medications to make the effort work – and non-profit aid associations such as the American Red Cross and the Salvation Army. The communication webs stretched across the country. Both Louisiana and Mississippi, along with relying heavily on the infrastructure and abilities of the private sector, also turned to the Strategic National Stockpile Program, to help supply needed medications. Its formulary, intended primarily to be of use in the case of a chemical or biological terror attack, did not fulfill all needs, but it certainly helped.

The logistics for those coordinating the efforts and

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Disaster

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those participating in them were daunting, to say the least. Palombo related some of the factors his company faced in sending a mobile pharmacy to help a hospital near New Orleans. Medco sent two trailers, he said, one to serve as a pharmacy, the other as living quarters for the staff, as no other accommodations were available. The relief teams had to be self-sufficient; local resources were not an option. "[The trailers] were being shipped from Ohio, because there wasn't any local source," said Palombo. "We had to bring fuel in on a van."

The joint undertaking worked to a surprising degree. Thanks to ingenuity, communication, and unrelenting efforts from both the private and public sectors, and despite the fluid shelter situation and the constant movement of displaced residents, evacuees got their medications, and hospitals and nursing homes received appropriate medications and supplies.

Important Points

In their presentations, Dufour and Broussard highlighted a number of points important for boards to consider as they revamp or create their own disaster plans, as did the remaining speaker who joined in for the second half of the continuing education session: Captain Christopher Jones, regional emergency coordinator for the US Department of Health and Human Services' (HHS) Office of Public Health Emergency Preparedness.

With the overriding importance of communication and coordination in the face of a catastrophe, Boards should consider their relationships with those agencies charged with the medical aspects of disaster response – now, when things are calm, said Jones. "The last thing you want to do during a disaster is come to your state health department or to your state emergency management agency and pass your business card to them and tell them who you are and where you're from and try to begin to figure out at that juncture what you can do to help," he said. "What you really need to be doing is approaching the state health departments and the state emergency management agencies, but primarily the state health departments, because they're the ones who'll be coordinating the health and medical response, sitting down with them and figuring out how the state board of pharmacy can lend a hand and become integrated into the plans, adapt the plans to meet the capabilities and resources that the state boards of pharmacy bring."

Another, related and important step for Boards is to examine their current regulations, Broussard suggested. Louisiana's comparatively new section providing "state of emergency" capabilities to provide emergency medications and accept the help of pharmacists not licensed in the state proved vital to the Board's ability to help the thousands in need. While many states have 72-hour emergency prescribing provisions, few go beyond this.

State boards might want to consider other regulations as well, such as one recommended in the federal government's report, "Katrina – Lessons Learned" (available at www.whitehouse.gov/reports/katrina-lessons-learned). In Louisiana, Broussard noted, the Board had to remind pharmacists that medications stored above 104° F for more than 24 hours could no longer be dispensed – something of a problem in the heat of a Gulf Coast summer with no electricity in sight. The Bush Administration's report suggests that states enact legislation requiring pharmacies to have generators, at least partially addressing situations like this. (Fuel for the generators following a large-scale disaster? That is another question.)

While it is difficult to plan for a situation that has not occurred, boards should try to brainstorm the logistical issues that might be faced in any disaster, and work to address them, Dufour said. As they think through various disaster scenarios, boards should keep potential logistical problems in mind. As an example, he raised several questions: How does the current infrastructure work? If that infrastructure broke down, how could the logistical challenges be met? Where could medications be stored, and how would they be unloaded, stored, and distributed?

Boards also need to plan how they will communicate with pharmacists and, potentially, the public during a disaster. "You should have newspaper ads, radio ads, information you can put on your Web site," said Dufour. "Have that in the can now, so if something does hit, you're prepared."

The boards should not ignore their own needs. Broussard pointed out the importance of safeguarding board records, for example. "We need to be mindful of our duty to protect records so we have continuity of operations," he said.

As the session's speakers noted, and as is echoed in disaster plan advice from private, public, and non-profit experts alike, responses to disasters do not begin at the federal level. While some criticize this policy – in the federal government's Katrina report, the authors recommend, "In a catastrophic scenario that

overwhelms or incapacitates local and state incident command structures, the federal government must be prepared to assume incident command and get assistance to those in need until state and local authorities are reconstituted" – at present, said Jones, "The bottom line . . . is that during a disaster, all disasters are local disasters. The local emergency management agencies have the foremost responsibility in coordinating the response. It's only after the disaster exceeds their capabilities and capacity to respond that they'll ask for assistance from the state. Once the state determines that the magnitude of the event exceeds their resources to respond . . . they ask the federal government for assistance."

Indeed, Jones said, "Every community and every state should plan for the worst. If you plan to be able to initiate a response and sustain the support for that response for a week, you'll be in good stead. Prior to Katrina . . . I said plan to sustain a response for 72 hours . . . Katrina taught us a grave lesson, that in a catastrophic event that encompasses many communities over such a broad geographic area, there aren't enough federal resources to go around."

Beyond Hurricanes

Katrina taught everyone a lot about catastrophes and large-scale disasters as they pertain to hurricanes, but what about other types of disasters? How transferable are Katrina's lessons? The Department of Homeland Security's National Response Plan identifies 15 types of incidents that could be deemed disasters or emergencies. Any given locality may be subjected to a natural disaster, a terrorist attack, or even what Jones referred to as "technological disasters" and "immigration events."

While some response elements remain the same, one disaster that would require a different response in many ways than a hurricane is a flu pandemic. How would the board continue operations with significant absenteeism, such as could occur at the height of a pandemic? How could pharmacies continue to operate? How would large numbers of people receive vaccinations, antiviral drugs, or other measures that might be necessary on a large scale and in a hurry?

In light of immediate concerns raised by the avian flu pandemic and concerns that it will eventually make the leap to easy transmission by humans, HHS has provided extensive guidance on planning for a flu pandemic. (See www.hhs.gov/pandemicflu/plan and www.pandemicflu.gov for the HHS plan and guidance for state and local entities, state plans, and other useful information on the topic.) HHS has pledged to support affected states or areas by such measures as conducting outbreak investigations, working to produce and distribute vaccines, and providing guidance on such community containment strategies as quarantines or travel restrictions.

HHS also recommended that state and local governments establish a Pandemic Influenza Coordinating Committee representing a wide range of specialties in the public and private sectors "to oversee preparedness planning and ensure integration with other emergency planning efforts." HHS convened a meeting of local and state officials from across the country in December 2005, and since then has held pandemic planning summits across the country. Plans have been drawn up and are public record in at least draft form for each state. If they have not already been involved in such planning and coordination efforts, boards of pharmacy should begin participating as soon as possible.

A side benefit of the focus on pandemic flu preparations is the light they can shed on other planning efforts that may or may not be moving forward, particularly other infectious disease emergencies, including bioterrorism events. They also may facilitate the communication and coordination necessary for effective planning for other, less similar disasters.

Despite recent attention focused on the issue, particularly in relation to a flu pandemic, tight budgets and busy officials pushing the matter off in favor of items that seem more urgent mean that disaster plans in general are being talked about more then actually created (or old ones seriously reviewed). As a result of Resolution 102-4-06, Emergency Preparedness, Response, and the US Distribution System, which was adopted at the Association's 102nd Annual Meeting in April 2006, NABP will convene a task force to examine the disaster plan situation and offer more specific guidance to the Boards on the topic.

Hurricane Katrina pointed up many faults in local, state, and federal ability to respond effectively to an event of catastrophic proportions. But it also highlighted some positives: far-sighted, emergency-triggered regulations that facilitated assistance efforts; flexibility, ingenuity, and sacrifice on the part of numerous members of the public and private sectors; and close cooperation between regulators, retailers, wholesalers, and manufacturers that allowed victims (and rescuers) to access needed medications. With comprehensive and well-thought-out plans for every jurisdiction, these positive elements can make the next big disaster less tragic.

July 2006

Emergency

Louisiana Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

5615 Corporate Blvd, Suite 8E, Baton Rouge, LA 70808-2537
www.labp.com

Emergency Preparedness and Disaster Response (06-07-248)

As we enter a new hurricane season, the Lousiana Board of Pharmacy believes it worthwhile to review some of the lessons learned in the aftermath of Hurricanes Katrina and Rita in the summer and fall of 2005.

Preparations

- Help your patients prepare for the hurricane season by providing them with copies of their patient profiles, and encourage them to keep that profile with their critical documents during an evacuation. **Communicate before they evacuate!**
- Help your pharmacy prepare for the next emergency by reviewing your data security and environmental control policies and procedures. We know that you backup your electronic prescription data on an appropriate schedule; are any of those backup copies stored off site? If you need to close the pharmacy for evacuation, try to prepare multiple copies of your data, preferably on different media. This could be useful if you have an opportunity to re-open your pharmacy using different computer equipment.
- If your prescription drug inventory includes items labeled for storage at "controlled room temperature" (most non-refrigerated oral solid dosage forms), what measures do you have to ensure the continuity of those temperatures in the absence of electricity from your local electrical power generation or distribution company? Have you considered the use of supplemental electrical generators to ensure appropriate temperatures for the storage of prescription drugs? If you do use such devices, please adhere to the safety precautions affixed to those devices.

Responses

- If the emergency situation was serious enough to prompt the Office of the Governor to issue a proclamation declaring a State of Emergency for some or all of the state, and if your pharmacy is operating within the area under the declaration of emergency, please remember two standing rules already approved by the Board:
  1. Using sound professional judgment, a pharmacist may dispense a one-time emergency prescription for any medication, for up to a 30-day supply, **if**
     a. in the pharmacist's professional opinion, the medication is essential to life or the continuation of previously prescribed therapy, **and**
     b. the pharmacist prepares a written record marked "Emergency Prescription," and then files and maintains that record as required by law.
  2. If you are assisting a shelter or other relief effort, that organization may accept offers of assistance from pharmacists from other states, even if not licensed in Louisiana. They must present and retain on their person a copy of a valid license in another state.

Remember, these rules are already in place; they are triggered by the governor's declaration of a State of Emergency.

- If you need to change the location of your pharmacy, please contact the Board office for assistance with that process. We may be able to streamline certain requirements for you.

State of California Department of Consumer Affairs

Memorandum

To: **Licensing Committee** **Date: Sept. 7, 2006**

From: **Board of Pharmacy – Virginia Herold**

Subject: **Overview of 340B Programs**

The board recently received materials regarding 340B Drug Discount Programs. Periodically, the board receives questions about such programs.

A copy of this material is follows.

340B™

Access Solution

An Overview of the 340B Drug Discount Program

How to Decrease Medication Costs for Patients

A Wellpartner Primer

Wellpartner®

Your Personal Pharmacy

Introduction iii

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Introduction

340B Program Overview

The 340B drug pricing program represents an outstanding opportunity for qualified Community Health Clinics, Disproportionate Share Hospitals, and other safety-net organizations to increase access to low-cost medications for their patients. While the 340B program has many benefits, a strong foundation in understanding how the program can be applied to maximize the benefits available from using this program is essential. Wellpartner has developed this 340B Primer to help readers establish a solid understanding about how the program operates and how organizations can benefit from its use.

The Primer is organized into five chapters. Readers may elect to read each chapter in succession, or only the specific chapter that addresses an area of interest about the 340B program. It by no means an exhaustive study of the 340B program, but is intended to help the reader establish a solid foundation on which to build. At the conclusion of this Primer, we offer a reference list of additional resources you may wish to review to help you expand your understanding of a particular 340B program area.

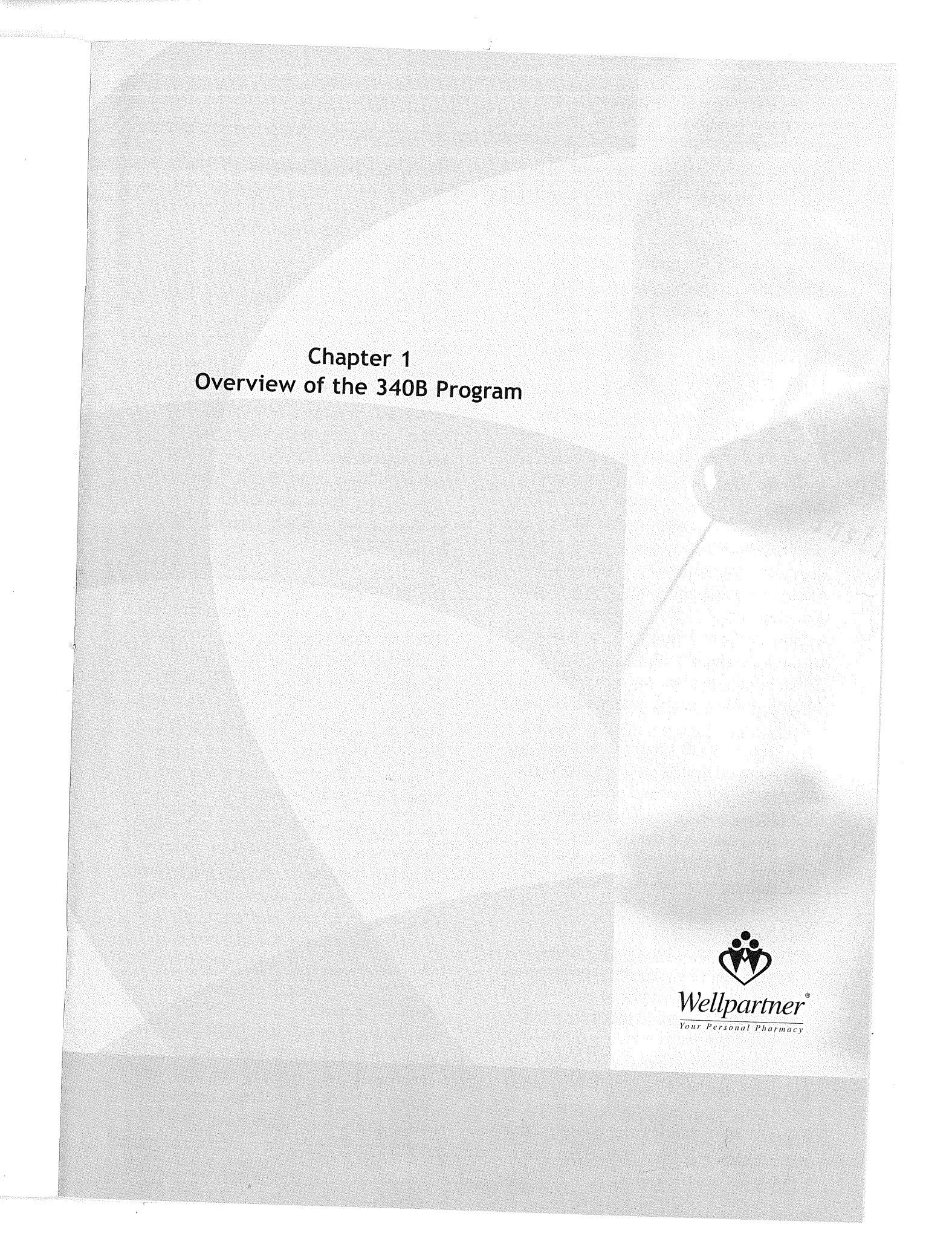
About Wellpartner

Wellpartner is a leading provider of 340B program solutions for qualified Community Health Clinics, Disproportionate Share Hospitals, and other safety-net providers nationwide.

With its 340B Access Solution™, Wellpartner offers qualified organizations a turn-key 340B Pharmacy solution that provides savings on medications while providing patients with increased access to lower cost prescriptions. Wellpartner's 340B Access Solution is a valuable resource for safety-net organizations that allows them to maximize their missions to serve the underserved, while delivering outstanding patient care.

Wellpartner has established close working relationships with the State and Federal agencies and organizations that are directly involved with the implementation and utilization of the 340B program. Through these efforts, Wellpartner is able to deliver effective and innovative methods for increasing utilization and support of the 340B program for its clients and partners.

Chapter 1
Overview of the 340B Program



Wellpartner®
Your Personal Pharmacy

Chapter 1 - Overview of the 340B Program

This chapter provides readers with a high level overview of the 340B program. It is intended for audiences who are new to the 340B program and who wish to gain a basic understanding of how this program operates. At the conclusion of this chapter, readers will understand who can participate in the 340B program and the requirements for getting started.

What is the 340B Program?

When Medicaid rebates were standardized with the Omnibus Reconciliation Act of 1990, an inadvertent side effect occurred that increased medication prices to health care safety-net providers, including Disproportionate Share Hospitals and Community Health Centers. This oversight was subsequently rectified with the passage of the Veterans Health Care Act of 1992, which inserted Section 340B into the Public Health Service Act.

The Section 340B program, also known as Section 602 or "PHS" pricing, is a federally administered program that allows certain qualified entities ("covered entities") within the health care safety-net to purchase outpatient medications at or below a defined discount price. The 340B program was intended by Congress to assist covered entities with stretching their limited federal funds to better serve the pharmaceutical needs of uninsured patients and other vulnerable populations.

Section 340B created a pricing structure for safety-net providers and established eligibility requirements for "covered entities" (i.e., entities eligible to participate in the 340B program) that allowed these organizations to realize substantial cost reductions on medications used for patients in an outpatient setting.

In addition to defining eligibility requirements for participation in the 340B program, the statute also mandated the establishment of a "Prime Vendor." The Prime Vendor is a single "preferred" purchasing agent that specializes in serving covered entities in the 340B program, and manages price negotiation and drug distribution responsibilities on behalf of qualified entities. The Prime Vendor for the 340B program is Healthcare Purchasing Partners International (HPPI).

The 340B statute established the Health Resources and Services Administration (HRSA) within the U.S. Department of Health and Human Services (DHHS) as the supervising agency for the 340B program. Within HRSA, the Office of Pharmacy Affairs (OPA) administers the 340B program.

Who Can Participate?

Only eligible institutions and patients can participate in the 340B program. The OPA has issued specific guidelines that outline participation criteria. The following is a brief description of the eligible institutions and patients who can take advantage of this program.

Entity Eligibility

Eligibility for participation in the 340B program is determined by entity status, specifically by receiving one of several grants or by being a certain type of Disproportionate Share Hospital or

Federally Qualified Health Center Look-Alike. Specifically, eligibility is limited to:

1. Federally Qualified Health Centers (FQHC), including:
   a. Consolidated Health Centers
   b. Migrant Health Centers
   c. Health Care for the Homeless
   d. Healthy Schools and Healthy Communities
   e. Health Centers for Residents of Public Housing
   f. Office of Tribal Programs or Urban Indian organizations

2. FQHC Look-alikes

3. Family Planning projects receiving a grant or contract under Sec. 1001 PHSA

4. Ryan White CARE Assist entities, including those receiving a grant under Subpart II of Part C of Title XXVI of the Ryan White Care Act (RWCA), relating to categorical grants for outpatient early intervention services for HIV disease, and Early HIV Intervention Services Categorical Grants

5. State-operated AIDS Drug Assistance Programs (ADAPs)

6. Black Lung Clinics

7. Comprehensive Hemophilia Diagnostic Treatment Centers

8. Native Hawaiian Health Centers

9. Urban Indian organizations

10. Certain entities that receive assistance for HIV Health Care Services

11. Entities receiving funds for treatment of sexually transmitted diseases or treatment of tuberculosis through a State or unit of local government, but only if the entity is certified by the Secretary of DHHS

12. Certain Disproportionate Share Hospitals.

Patient Eligibility

In order to gain access to medications, a patient who receives a medication through the 340B program must be a patient of the covered entity. This requirement was established to protect against the risk of diversion of 340B program products to non-qualified patients. Though the statutory definition of a qualified patient remains somewhat vague, OPA has issued guidelines intended to clarify this definition. The definition of a patient who qualifies to receive medications at 340B program prices is codified in 60 FR 39762:

> "An individual is considered a patient of a covered entity (with the exception of State operated or funded AIDS drug assistance programs) only if:
>
> (1) The covered entity has established a relationship with the individual, which includes maintaining records of the individual's health care;
>
> (2) The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral

for consultation) such that responsibility for the individual's care remains with the covered entity;

(3) The individual receives a health care service or range of services for which grant funding or federally qualified health center look-alike status has been provided. (Disproportionate share hospitals are exempt from this requirement.)"

Restrictions and Requirements

While the 340B program is intended to increase access to low-cost medications for safety-net providers, there are four significant restrictions or requirements that qualified entities must comply with in order to gain access to this program. These requirements are meant to ensure that only specific patients and facilities have access to drugs purchased at the 340B price, and that each drug is not subject to multiple discounts and rebates.

- **Prohibition on "Double-Dipping"**– Covered entities shall not request 340B prices for the same drug for which Medicaid will request a rebate. With this prohibition, a covered entity can receive a discount through the 340B program or Medicaid can receive a discount via rebate, but both may not occur for the same drug.

  In order to prevent "Double Dipping," entities participating in the 340B program are required to either utilize non-340B medication for Medicaid patients, or to bill their state Medicaid agency the actual acquisition cost of the medication, plus a dispensing fee. This prohibition does not apply to Managed Medicaid patients where the State does not pay directly for the medications.

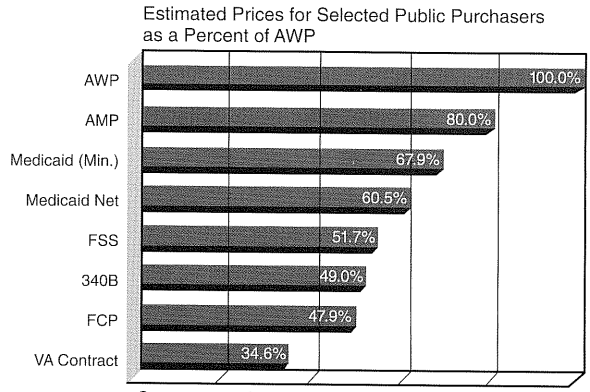
- **Prohibition for resale of drugs or "Diversion"** – With any covered outpatient drug purchased using 340B prices, a covered entity shall not resell or transfer the drug to a person who is not a patient of the entity. Diversion is the distribution of 340B medications to non-340B eligible patients, either intentionally or unintentionally.

  In order to gain access to 340B medications, patients must meet the definition of a patient reviewed ear lier in this chapter. It is important to note a patient who is referred out of a qualified entity to a contractually affiliated provider (e.g., under an HMO) is still considered a covered patient of the entity and is entitled to receive medications at 340B prices.

- **Outpatient Only** – Drugs purchased through the 340B program cannot be utilized in an in-patient setting. 340B prices are available only to qualified patients receiving prescriptions in an outpatient setting only.

- **Audit Requirement** – Covered entities must maintain accurate records documenting that the entities are not "Double-Dipping" or reselling, or transferring drugs to persons who are not patients of the entity. The Federal government, drug manufacturers, and affiliated organizations

have the right to audit a participating entity's dispensing records to ensure that there is no "Diversion" or "Double-Dipping." Participating entities have the statutory requirement to ensure the maintenance of accurate records.



Source: von Oehsen, Pharmaceutical Discounts Under Federal Law: State Program Opportunities 05/03

340B Program Pricing

It is important to note that the 340B program is not a governmental purchasing program. It is a discount program administered by the Federal government.

340B program pricing offers significant savings over normal retail pharmacy reimbursement rates. For example, medications purchased through the 340B program are approximately:

- 51% less than the Average Wholesale Price (AWP);
- 39% less than the average insurance reimbursement; and
- 19% less than the average Medicaid price, net of rebates.

340B pricing is derived from a manufacturer's participation in any Medicaid program. As a requirement for contracting with Medicaid, pharmaceutical manufacturers are required to make their products available to covered entities at or below a statutorily defined "ceiling price." The 340B price is the "ceiling price," meaning it is the most that covered entities can be charged for medications purchased directly from wholesalers. Participating entities have reported savings that range between 25-50% for covered outpatient drugs as a result of the low 340B price.

The 340B program "ceiling price" is just that, a ceiling price. Covered entities are allowed, and in fact are encouraged, to negotiate sub-ceiling prices either with manufacturers and/or wholesalers.

Getting Started

Getting started in the 340B program requires the following steps:

1. Determine if the entity is eligible by contacting the Office of Pharmacy Affairs at www.hrsa.gov/odpp.
2. Submit a 340B Program Registration Form for Covered Entities. Forms can be downloaded from the Office of Pharmacy Affairs web site (the listing is updated by OPA once a quarter, so plan accordingly).
3. Select a pharmacy wholesale distributor. Currently, the "big 3" wholesalers (McKesson, Cardinal, and Amerisource Bergen) are

actively participating in the 340B program. It is also strongly recommended that entities participate in the 340B Prime Vendor program to maximize 340B program savings. The Prime Vendor program allows the covered entity to gain access to additional sub-ceiling pricing while also allowing it to maintain any existing purchasing agreements, to include wholesaler agreements.

If electing to use a Contracted Pharmacy (see Chapter 2 – "Contracted Pharmacy Services"), the entity must submit a Contracted Pharmacy certification form. This form is also available on the OPA web site.

Setting Up 340B Pharmacy Services

Covered entities may provide 340B pharmacy access for their patients via any of three methods. These are:

1. **Clinic Dispensary** – An on-site dispensing cabinet utilizing a small inventory of basic medications.

2. **In-House Pharmacy** – A full-service pharmacy created and operated by the entity on its premises.

3. **Contracted Pharmacy** – An external pharmacy (e.g.,Wellpartner) under contract with the covered entity to provide pharmacy services to the entity's patients.

Further analysis and discussion of these models can be found in the next chapter of this Primer: "Contracted Pharmacy Services."

Chapter 2
Contracted Pharmacy Services

Wellpartner®
Your Personal Pharmacy

Chapter 2 - Contracted Pharmacy Services

This chapter provides the reader with an understanding of how a 340B pharmacy access model can be created, and the benefits that are available to organizations that effectively manage them. A discussion of the role and merits of various 340B implementations, with an emphasis on the Contracted Pharmacy model, is reviewed.

While this chapter specifically discusses Contracted Pharmacy service arrangements, it is important to understand that there are additional options available to the qualified entity for providing pharmacy services under the 340B program. These options are briefly touched on in this chapter.

Methods for Providing 340B Pharmacy Services

When the 340B program was established in 1992, it was expected that eligible entities would deliver pharmacy services through either internal dispensing facilities or at on-site clinic dispensaries. However, these options proved problematic for many entities. The Health Resources and Services Administration (HRSA) published guidelines in 1996 that allowed for the provision of 340B pharmacy services through a "Contracted" pharmacy, which enabled facilities to contract with a local community pharmacy or other outside pharmacy to act as its agent to dispense medications using 340B prices.

With the publication of Contracted Pharmacy Guidelines in 1996, HRSA established three methods for covered entities to provide 340B pharmacy services to their patients. However, the exact implementation of each of these methods has continually evolved with new methods becoming authorized with increasing frequency. While each of the 340B pharmacy fulfillment models has its strength and weakness, there is always a process for refining each implementation to ensure that it is appropriate to the entity's specific operating requirement.

The three 340B pharmacy fulfillment models are:

1. **Clinic Dispensary** – This method is the easiest and most common option for health centers to establish 340B pharmacy fulfillment,although it remains less common at other qualified entity types, such as hospitals. The Clinic Dispensary model enables an entity to purchase fewer medications and store them with their donated samples and manufacturer bulk donations. While this is a simple and low-cost option to initiate, it is cumbersome to process and manage. This method also eliminates any possible capture of third-party payor or Medicaid revenue for the health center to use as an offset to its indigent care program costs.

2. **In-House Pharmacy** – Most prevalent among Disproportionate Share Hospitals and government-funded health centers, the In-House Pharmacy option is the primary model that was envisioned when the 340B program was created. With this model, the entity develops and

operates an internal pharmacy on its premises, which allows the clinic to maintain complete control of the pharmacy operations and to capture any revenue associated with the 340B program. In addition, this model allows the pharmacist to become a fully integrated member of the clinical care of every patient at the health facility.

Creating an In-House Pharmacy is very expensive to initiate and operate. A nation-wide shortage of pharmacists introduces additional complexity to the health facility interested in creating an In-House pharmacy, due to the scarcity of qualified pharmacists and the increased salaries being commanded. Also, opening a pharmacy requires an ongoing commitment of human and capital resources to ensure compliance with state and federal laws, dedicated facility capacity, operations and management of the facility, and other similar concerns.

3. **Contracted Pharmacy** – The Contract Pharmacy model is becoming the preferred standard for qualified entities because it affords these organizations with complete 340B pharmacy access for its patients and requires minimal administrative or program resource costs to initiate or maintain operations. Once implemented, this model offers easy administration that is required by many entities, yet it allows for coverage of a complete range of medications. However, the Contracted Pharmacy model limits a patient's access to one Contracted Pharmacy per entity service delivery site. It also requires the entity to contract with a community pharmacy to provide these services. The qualified entity is required to ensure that the Contracted Pharmacy conforms to the strict 340B program requirements that protect against drug "Diversion" and "Double-Dipping".

340B Pharmacy Service Models

Model	Pros	Cons
Clinic Dispensary	• Inexpensive • Readily Implemented • On-Site	• Cumbersome Administrative Requirement • Lost third-party payer and Medicaid revenue • Limited to a narrow Range of 340B Medications
In-house Pharmacy	• Excellent Control • Convenient • Pharmacist on Clinical Team • Revenue Capture	• Resource Intensive • High Start-up Cost • Pharmacist Shortage • Administrative and Facility Requirements • Pharmacy Laws and Regulations
Contract Pharmacy	• Readly Implemented • Broad Range of Medications • Low Initial and On-Going Costs • Revenue Capture	• One-to-One Pharmacy Requirement • Administrative Requirements • Must Contract with a Pharmacy • Compliance Responsibility

340B Program Requirements and Restrictions

While providing pharmacy services using the 340B program is straightforward, there are certain program requirements and restrictions that an entity must comply with in order to conform to Federal guidelines for this program.

These requirements include:

Eligibility Requirements
In order to provide pharmacy services using a Contracted Pharmacy, both the entity and the patient must be eligible to participate in the 340B program. While eligibility is explored in greater depth in Chapter 1 of this Primer, a brief description of the eligibility requirements is explored below.

1. **Entity Eligibility**
   Eligibility for participation in the 340B program is determined by the status of the entity. Specifically, the entity must be the recipient of one of several Federal grants or be designated as a specific type of Disproportionate Share Hospital or Federally Qualified Health Center Look-Alike.

2. **Patient Eligibility**
   Patient eligibility is determined by the status of the individual as a patient of the covered entity. Simply providing pharmacy services is not sufficient to qualify an individual as a patient of the covered entity.

There are two further requirements for patient eligibility:

- "Diversion" – With any covered outpatient drug purchased using 340B prices, a covered entity shall not resell or transfer the drug to a person who is not a patient of the entity. Diversion is the distribution of 340B medications to non-340B eligible patients, either intentionally or unintentionally. In order to gain access to 340B medications, patients must meet the previously discussed definition of a patient.

  It is important to note that a patient who is referred out of a qualified entity to a contractually affiliated provider (e.g. under an HMO) is still considered a covered patient of the entity and is entitled to receive medications at 340B prices.

- Outpatient Only – Drugs purchased through the 340B program cannot be utilized in an inpatient setting. 340B prices are available only to qualified patients who receive prescriptions in an outpatient setting only.

Purchasing Requirements
Since the 340B program is an entity-specific drug discount program, the entity is the only organization that can legally purchase 340B medications. Therefore, the Contracted Pharmacy must operate under a "Bill-to/Ship-to" arrangement, where medications are shipped by the drug wholesaler directly to the pharmacy and the bill for the medications is sent to the entity.

"One-to-One" Pharmacy Requirement
Under current HRSA program guidelines, a covered entity is only allowed to provide Contracted Pharmacy services through a single pharmacy location (either internal or contracted) per service delivery site. This requirement is most problematic for hospitals, if they have an outpatient pharmacy in operation, as this is considered to be the pharmacy services delivery site for the hospital. However, HRSA program guidelines allow for a Contracted

Pharmacy to be the same pharmacy for multiple service delivery sites. Thus, an entity with three delivery sites may contract with the same pharmacy for all three delivery sites in an arrangement commonly referred to as a "multi-to-one" relationship.

There is an exception to the one-to-one Contracted Pharmacy limitation. In 2001, HRSA announced the availability of Alternative Method Demonstration Project waivers, which allow covered entities to submit a waiver request to HRSA to grant an exception to the one-to-one pharmacy restriction. This topic is explored in greater detail in Chapter 3 - "Networks and Novel Methods".

Restriction on "Double-Dipping"
As discussed in Chapter 1-"Overview of the 340B Program," under the "Double-Dipping" prohibition, a covered entity can receive a discount through the 340B program or Medicaid can receive a discount via rebate, but both may not occur for the same drug. In order to prevent this, entities participating in the 340B program are required to either utilize non-340B medication for Medicaid patients, or to bill their state Medicaid agency the actual acquisition cost of the medication, plus a dispensing fee. This prohibition does not apply to Managed Medicaid patients where the State does not pay directly for the medication.

Audit Requirements
Covered entities and their Contracted Pharmacies must maintain accurate records documenting that the entities are not "Double-Dipping," diverting, reselling or transferring drugs to persons who are not patients of the entity. The federal government, drug manufacturers, and affiliated organizations have the right to audit a participating entity's dispensing records to ensure that there is no "Diversion" or "Double-Dipping". Participating entities have the statutory requirement to ensure the maintenance of accurate records for prescriptions that are dispensed using 340B program prices.

Inventory Requirements
Only one state (Florida) has a requirement that there be a separate physical inventory. Every other state – and Federal guidelines – provide an option to maintain a "virtual inventory" of 340B products to prevent drug diversion.

Historically, virtual inventory control has been problematic for many Contracted Pharmacies. HRSA has authorized the creation of a "Replenishment Model" that enables Contracted Pharmacies to manage their 340B inventory virtually while receiving 340B replacement product on a replenishment basis.

The replenishment capability allows a Contracted Pharmacy to dispense medication to 340B-covered patients from its own inventory, and then have that inventory replenished by the covered entity. In effect, the Contract Pharmacy "loans" the covered entity the medication and the covered entity then orders replacement inventory.

The advantage of this approach to 340B in a Contracted Pharmacy setting is that it reduces the likelihood of drug

"Diversion," as there is no specific 340B inventory sitting on the Contract Pharmacy's shelves.

Additional Restrictions or Requirements

While HRSA's guidelines are uniform for the entire country, State, Local and grant-making organizations can require restrictions and controls that surpass Federal Guidelines. The entity is strongly encouraged to check with its local State Board of Pharmacy and with its grant-making organization before deciding upon a specific model to manage 340B pharmacy fulfillment.

The Mechanics of a Contract Pharmacy Relationship

When establishing a contracted 340B pharmacy there are multiple steps required to ensure the program operates smoothly and complies with program requirements and restrictions. Some of these steps are necessary from a regulatory perspective, while some are technically optional but important to ensure a smoothly functioning 340B program.

Required Regulatory Steps

- **Select the Contracted Pharmacy** – This is often the most difficult step, as many pharmacies are unable or unwilling to comply with the requirements of the 340B program, or will charge such an exorbitant dispensing fee as to make the program ineffective from a cost perspective. In addition, some pharmacies may be willing partners but may be unable to successfully administer the program.

- **Register the Contracted Pharmacy Relationship with the OPA** – OPA requires that all contracted pharmacies be registered before actual

  dispensing can occur. Contracted Pharmacy certification forms can be found on the OPA web site.

- **Select a Wholesale Drug Distributor** – Because of the purchasing requirements described earlier, the covered entity is the organization that purchases medication under the 340B program. Therefore, a covered entity must have a contract with a drug wholesaler to purchase medication at 340B program prices. Currently, most national wholesalers participate in the 340B program and are willing to work with covered entities on purchasing agreements.

  It is recommended that the entity contract with the same wholesaler that the Contracted Pharmacy uses in order to reduce the disparity between the specific National Drug Code Numbers (a unique identifying number for each medication that may or may not be carried by all wholesalers) that the pharmacy has to support.

- **Submit Medicaid Number to OPA** – This is a necessary step to ensure that a Medicaid rebate is not requested on medication purchased through the 340B program for Fee-for-Service Medicaid clients.

- **Determine Inventory Control Process** – In order to prevent "Diversion," it is necessary for the covered entity and the Contracted Pharmacy to agree upon on a method to control inventory. As previously discussed, there are several methods to control inventory, including maintaining a separate physical inventory, creating a "virtual inven tory", and/or establishing a "replenishment" inventory system. Each inventory management option has unique strengths and weaknesses. However, it is advisable that clients adopt a "replenishment" system, as this method is the most effective means to prevent drug "Diversion" and "Double-Dipping", while also providing an option for the lowest costs and resource requirements for the entity.

Optional but Important Steps

The following list of optional but important steps is by no means exhaustive. While not required by HRSA, these recommendations are advised as necessary prior to implementing a 340B pharmacy program.

- **Establish Pricing Model** – Aside from the requirements associated with grants (e.g. Section 330 grants and Share-of-Cost), pricing for 340B medications is determined by the entity. It is important to consider that the difference between acquisition costs and typical reimbursement from third-party payors provides an effective revenue source for the entity. Therefore, prior to commencing a 340B pharmacy operation, the entity should determine a pricing model that is appropriate to the patient population served by the entity. For example, the entity may decide to charge subsidized or sliding-cost patients only the dispensing fee, and to charge all other patients full-price, plus a dispensing fee. Whatever pricing model is selected, the entity will need to work with the pharmacy to establish how the patient's charges and insurance reimbursements are collected and allocated.

- **Determine Reports Required from the Pharmacy** - In order to successfully manage and administer the 340B program, the covered entity must have a firm understanding of how the program is performing. To do so, the entity must agree on a series of standardized reports that the Contracted Pharmacy will generate on a periodic basis.

  For example, with Wellpartner's Access Solution™, the pharmacy provides three reports: a Dispensing Record Report, an Inventory Ordering Report, and a Revenue Reconciliation Report. These reports assist an entity with understanding and administering its 340B program, and includes information that details product and patient utilization, thereby assuring itself of the information necessary to ensure the facility remains in compliance with 340B program requirements.

- **Create a Preferred Drug List** – One of the unique characteristics of

the 340B program is that pricing is not self-evident. In many cases, the cost of a generic equivalent for a brand-name medication may actually be higher than the brand. It is recommended that an entity create a Preferred Drug List that takes this into account. In addition, by restrict ing the number of medications supported by an entity, the facility can reduce the number of supported NDCs, thus creating an opportunity to buy medications in larger quanti ties (which will result in lower net cost to the entity).

For many organizations, the 340B program is best implemented using a Contracted Pharmacy arrangement. This approach enables an entity to quickly take advantage of the drug discounts available through the 340B program. Adequately implemented and managed, a 340B Contracted Pharmacy program can provide additional savings and revenue options while minimizing critical entity resources to administer its operation.

Establishing a Contracted Pharmacy may seem complex. It truly does not need to be. When creating a Contracted Pharmacy, it is important to select a pharmacy provider that can guide the entity through the implementation process and ensure that the entity remains in compliance with the various 340B program management require-ments. The ideal Contracted Pharmacy partner will help the entity understand how it can implement the program to take full advantage of the program within the clinic's service area.

Chapter 3
Networks and Novel Methods

Chapter 3 - Networks and Novel Methods

This chapter explores the various non-traditional methods for delivering pharmacy services to patients of qualified 340B entities. On its surface, gaining an "Alternative Method Demonstration Project" waiver may appear complex. This chapter is intended to assist the reader with determining whether a waiver is appropriate and, if so, how to implement either a network or novel method for accessing 340B pharmacy services under this provision. At the conclusion of this chapter, the reader will understand the role an Alternative Method Demonstration Project can play in helping the organization expand access to 340B programs and prices.

Alternative Method Demonstration Project Waivers

As we learned in Chapter 2, when the Health Resources and Services Administration (HRSA) published guidelines in 1996 creating "Contracted" pharmacies for 340B pharmacy fulfillment, safety-net providers were authorized to contract with community pharmacies as a means to provide discounted medications to their patients. These guidelines limited safety-net providers to "one-to-one" pharmacy relationships (that is, one pharmacy to one service delivery site).

While the Contract Pharmacy guidelines were instrumental to increasing access to 340B prices, they also proved limiting to a great number of entities, including entities that operated on-site pharmacies or required collaborative networks of entities. Citing the need to "increase access to 340B-priced pharmaceuticals," in 2001 HRSA announced guidelines for entities to establish 340B pharmacy programs outside of the standard models that had been created. These guidelines established "Alternative Method Demonstration Project" (AMDP) waivers and created a vehicle for safety-net providers to establish methods for delivering pharmacy services outside of the defined "one-to-one" relationship for 340B pharmacy fulfillment.

Administered by the Office of Pharmacy Affairs (OPA) within HRSA, AMDP waivers offer 340B-eligible entities the ability to operate projects and programs outside of the 340B Program guidelines when the current guidelines do not provide benefits to the covered entities. AMDP waivers are required to be time-limited (lasting no more than three years) and are subject to review to ensure compliance with 340B regulatory and program requirements. If an approved AMDP method is determined to be a success, the waiver method can be incorporated into the 340B program's published guidelines.

Alternative Method Demonstration Project Models

AMDP waivers may be approved for many different models, but the basic features of a waiver can be defined in one or more combinations of a few methods. Methods that can be utilized through an AMDP waiver include:

"One-to-Many" Method

In a "One-to-Many" method, one site may have multiple locations that provide

340B pharmacy fulfillment to its patients. An example of this method is one where a site has an on-site pharmacy or a dispensary (in States that require dispensaries to hold a clinic pharmacy license), and wishes to supplement its access to 340B prescriptions by contracting with one or more retail or mail-order pharmacies.

"Many-to-Many" Method

"Many-to-Many" methods can be segregated into two categories by the number of entities involved in the method:

1. **Single Entity** – Under existing Contract Pharmacy guidelines, a single entity that has multiple service delivery sites is limited to one pharmacy per service delivery site and, with some small and unique exceptions, patients are not allowed to have their prescriptions filled at pharmacies that are not directly affiliated with the site where they received their medical care. Accordingly, many entities choose to file an AMDP waiver that will allow their patients to fill their prescriptions at any of their affiliated pharmacies and additional Contracted Pharmacies. This method is the most readily approved option, and has significant impact on patient access.

2. **Multiple Entities** – Multiple covered entities may decide to create a pharmacy network that allows patients from any of the covered entities to select any of the affiliated pharmacies, including on-site and Contracted Pharmacies, to fill their prescriptions. This type of pharmacy network has many distinct advantages, but requires a more complex system of controls. It is required that one entity be the prime entity under such an arrange ment, and it is usually more effective to have a dedicated party control the network to ensure all aspects of the network remain in compliance with 340B statutory and program requirements.

"Unique" Methods

The "Unique Methods" approach is a broad generalization of demonstration alternatives that encompass many various innovative models. As an example, one AMDP waiver that has recently been approved authorized a tele-pharmacy solution incorporated with remote controlled dispensing devices at two rural clinics, in addition to multiple on-site and Contracted Pharmacies integrated into the 340B pharmacy network.

OPA has stated that it will consider any innovative model that meets 340B program objectives. It is expected that an increasing number of AMDP waivers will be approved in the coming years as the federal government continues to seek new ways to expand access to 340B program prices for qualified patients.

Alternative Method Demonstration Project Criteria

Alternative method demonstration projects are not funded grant activities and waivers are not automatically approved. OPA requires that an applicant meet several distinct criteria in order for a

waiver to be granted. This section describes elements of the AMDP application. Entities interested in making a demonstration waiver application should ensure that the application includes these elements:

Demonstration of Need
Entities may determine that the current methods of utilizing the 340B program are not adequate and apply to OPA for Alternative Method Demonstration Project approval. The entity must establish to OPA's satisfaction why the currently allowed methods for pharmacy access are inadequate or unacceptable to the entity. It must also establish a demonstrated need for the AMDP waiver.

A demonstrated need applies to two separate aspects of the 340B program, including:

1. **Entity Need** – Why the entity cannot utilize published guidelines to provide 340B pharmacy access. Acceptable examples can include:

    a. Inconvenient hours of operation at current pharmacy site(s).
    b. Lone pharmacy location inconvenient or inaccessible to many patients.
    c. High administrative costs.
    d. Pharmacy services cannot be implemented realistically under current models.

2. **Community Need** – What benefits the community will receive from the AMDP proposal that are not currently available and how approval of the AMDP proposal will affect the community. To demonstrate community need to OPA's satisfaction, it is recommended that a waiver application include the following elements:

    a. Map(s) of sites and/or pharmacy locations to demonstrate proximity to the entity.
    b. Description of area served.
    c. Description of population served, including:
        - Poverty status
        - Insurance status
        - Population of target area
        - Number of prescriptions dispensed
        - Noncompliance rates
        - Notable prevalence of disease in area served
    d. Justify statements of need with data.

Description of the Method

In order for an AMDP application to have the greatest opportunity for approval, it is imperative that applicants ensure they adequately describe how the proposal will improve the entity's ability to provide access to 340B prices for its patients. This is the actual "meat" of the proposal, and is also the primary reason AMDP applications are denied.

In this section of the AMDP application, the waiver applicant needs to describe the plan for the network, what will be accomplished, and how it will be accomplished. When completing this section of the waiver request, it is absolutely imperative that the applicant address the "who, what, where, when, why, and how" of how the AMDP application will save the entity's mission.

Methods of Evaluation and Audits

Because the AMDP waiver is, ultimately, an evaluation of new 340B fulfillment methods, OPA requires that each AMDP application include an evaluation of the success of the method. Specifically, OPA requires applicants to address the following items:

- An evaluation of the project and its improvement on access to 340B medications, including the numbers of patients accessing the program and the number of prescriptions that are dispensed.
- An evaluation of actions to be undertaken to reduce administrative overhead, including control of additional costs that are incurred (if any).
- An evaluation of the procedures and actions to prevent "Diversion" and "Double-Dipping'.
- An evaluation of the value participation in the 340B brings.

OPA requires that "all demonstration projects undergo annual audits following standard business practices." OPA also requires that these audits be performed by an independent outside auditor with experience auditing pharmacies. Therefore, OPA requires the following information in the waiver application:

- Identification of the auditor.
- Description of the auditor's experience auditing pharmacies.
- Description of the program elements to be audited.
- Description of what items and reports will be provided to the auditor by the entities and pharmacies.

Identification of Participating Covered Entities

In order to participate in an AMDP waiver, all entities are required to be 340B eligible and listed in the OPA database of covered and participating entities. In addition, OPA requires that all entities demonstrate their commitment to the waiver application by including letters of support and/or contracts and agreements. In addition, if the waiver includes Contract Pharmacies, OPA requires that each Contract Pharmacy have in place the OPA Contract Pharmacy Certification.

Description of Inventory and Dispensing Controls

Because of prohibitions in the 340B program (e.g., prohibitions against "Double-Dipping" and "Diversion"), OPA requires a detailed description of the entire dispensing process, including inventory control, eligibility verification (of patient and provider), and purchasing processes. It is important to note that "Diversion" and "Double-Dipping" are of significant concern to OPA, and therefore information that discusses how these items are mitigated or eliminated should be thoroughly reviewed.

OPA requires that the AMDP waiver application address the following issues:

1. **Compliance with State Pharmacy Laws** – The waiver application should demonstrate that the proposed methods are in compliance with State pharmacy laws, including dispensary licenses, inventory controls, and adjudication methods. For example, in some states it is illegal for a third-party to seek reimbursement for a prescription on behalf of a covered entity.

2. **Description of Eligibility Verification** – The waiver application should detail the necessary controls that are in place to prevent "Diversion" of 340B medications to non-eligible patients. Eligibility verification should ensure that the entity and provider are eligible to participate in the network and the 340B program, and that the patient meets the definition of a patient as defined by OPA.

3. **Description of Dispensing and Inventory Control Procedures** – The waiver application must address inventory control, the methods used to manage inventory (e.g., separate physical inventory, virtual inventory, replenishment inventory, etc.), the procedures used to manage prescriptions that are not dispensed or picked-up, inventory ordering and allocation procedures, and other control processes. In addition, the application must describe the record-keeping system that will be put in place to ensure compliance with 340B program and regulatory requirements.

4. **Description of Medicaid Billing Procedures** – The waiver application must describe the system that will be used to ensure that there is no "Double-Dipping" of Medicaid rebates. Acceptable options to control against "Double-Dipping" include carving Fee-for-Service Medicaid prescriptions out of the 340B program, or adjudicating Medicaid 340B prescriptions at Acquisition Cost, plus the Medicaid dispensing fee.

5. **Description of the Financial Relationships** – The waiver application must also address the flow of money between all parties in the application. This includes adequately describing who will pay for the medications, what the reimbursement rate will be and how the reimbursements will be managed, who pays for subsidized patients (if any), and other details that describe the financial relationship of the demonstration proposal.

Description of and Information Regarding Contracted Pharmacies

Because of the potential for "Diversion", OPA requires additional information if Contracted Pharmacies are to be used in any AMDP waiver. OPA requests that the following points be addressed in the application:

1. **Certification of the Pharmacies** – OPA requires that the certification form for each Contracted Pharmacy be included in the waiver application. Contracted Pharmacy certification forms can be found on the OPA web site.

2. **Description of Pharmacy Reports** – OPA requires that the Contracted Pharmacies supply the covered entities with periodic reports. OPA requires that the waiver application detail:

   a. The information included in the reports from the Contracted Pharmacy.
   b. The frequency with which these reports will be produced.
   c. Procedures for handling discrepancies within the reports.

3. **Third Party Billing Procedures** – OPA requires that the waiver application verify that the intended third-party billing procedures that will be deployed are legal/authorized in the state(s) where the covered entity will operate the demonstration project. A description of the procedures that will be used to ensure accountability and accuracy of third-party reimbursements to the covered entity is also required.

4. **Description of Compensation** – OPA requires that the waiver application detail the compensation process, including procedures for, and frequency of, compensation to pharmacies contracted to provide 340B pharmacy services.

5. **Description of Inventory Controls** – As described previously, OPA requires that a waiver application detail the inventory controls that will be utilized. A detailed description of the methods for ordering, and the inventory model to be used, is required.

6. **Justification of Pharmacy Selection** – While OPA does not place a limit on the pharmacies selected, OPA does require a "reasonable" justification of the selection of the contract pharmacies. While OPA does not define "reasonable," a simple explanation of the selection process for each pharmacy is adequate.

7. **Description of Procedures for Addressing Discrepancies** – OPA requires that the waiver application detail the steps that will be undertaken to address any discrepancies that arise between the Contracted Pharmacies and the entity in administering this demonstration project relationship.

Description of Network Entities (If more than one entity)

Because many AMDP waivers cover multiple covered entities, there are some additional information requirements imposed on a waiver request that includes more than one covered entity.

These additional information requirements include:

1. Description and definition of the proposed network – OPA requires a description of the entity network that will be covered by the demonstration project. It is more likely that OPA will approve a multi-entity network request if the entities have any other affiliation.

2. Approval of State Administrative bodies – If a State administrative body provides oversight of the network, OPA requires a letter from this administrative body approving the network.

General Information and Descriptions

In addition to the specific topic items described above, there are additional items that OPA requires be included in an AMDP waiver application. These items include:

- A signed letter from each entity acknowledging that:
  - The entity's patients have the right to fill prescriptions outside of the proposed pharmacy network (though not at 340B pricing).
  - The proposed AMDP structure does not violate Medicaid and/or Medicare Anti-Kickback statutes.
  - The proposed AMDP structure complies with Board of Pharmacy regulations for the entity's State.
  - The entity is aware that the AMDP is subject to audit by manufacturers and HRSA.
- Copies of all contracts, agreements, or Letters of Understanding between all parties involved in the AMDP. Unsigned copies are acceptable.

Alternative Method Demonstration Project Mechanics

When developing an AMDP waiver, a covered entity will be well-served if it uses the outline of required elements outlined in this chapter as it prepares its proposal. However, to ensure a waiver application can be processed expeditiously and receive approval, entities may wish to include certain additional steps/actions that will help make the AMDP a successful project. These steps/actions are:

- **Identify a Project Manager for the network, for each entity, and for each site** – It is important to identify an individual who "owns" each portion of the AMDP to ensure smooth functioning of the overall network. Development and management of the network can be outsourced to an outside organization that is familiar with the complexities involved, but each entity and each site must maintain an individual with responsibility to become directly involved to ensure the model works.

  If the entity elects to use an outside organization to oversee the project in its entirety, it is important that the entity ensures the resource has a track-record of managing AMDP projects. This will help minimize mistakes and help expedite the application process.

- **Develop a network "Preferred Drug List" (PDL)** – Covered entities can limit complexity if they manage the number of medications that an AMDP network provides. Limiting the specific number of medications can make coordination and control of all the pharmacy elements less complex, and allows for greater purchasing power for all the covered entities.

- **Develop an "education campaign"** – The network will function more effectively if all stakeholders are aware of the network and how it can affect them. In order to make this information common knowledge, it is recommended that there be a targeted education campaign directed toward patients, providers and staff, State and local governmental officials, and the community.

  This education does not need to be extensive or expensive, and can be as simple as staff education days at each site, "Dear Colleague" letters to community providers and government officials, site-specific communication directed at patients, and public relations outreach directed at community media.

  By undertaking this effort, entities can help ensure the odds of success of their demonstration project increase.

- **Invite participation by major regional insurers** – By inviting Fee-for-Service and Managed Medicaid, as well as any Medical Assistance Programs and Third-Party payors to participate in the 340B network, covered entities are likely to engender greater goodwill and cooperation when trying to maximize the potential of the AMDP network. It may also reinforce greater participation and therefore enhance utilization among qualified patients.

AMDP waivers represent an excellent alternative for many safety-net providers to establish a method for delivering pharmacy services. Operating outside of the defined "one-to-one" relationship for Contracted Pharmacies, the successful demonstration project will increase access to discounted medications for their patients while adhering to the strong management and control mechanisms required of the 340B program.

Gaining an AMDP waiver requires organizational focus and commitment to complete the application process. However, OPA has assured the 340B community that it will assist entities seeking to develop an AMDP with completing the application process.

Additionally, by following the recommendations and tips offered in this chapter, the reader can increase the odds of success by understanding and preparing an AMDP waiver application.

Chapter 4
Wellpartner Innovative Strategies

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Chapter 4 - Wellpartner Innovative Strategies

This chapter builds upon the foundation of understanding that has been established from the previous chapters of this primer and explores some the expansion options that may exist for covered entities as they seek to maximize the value of the 340B discount program for their communities. After reviewing this chapter, readers will have a broader understanding of their program options, as well as an understanding of the Wellpartner solutions that have been developed to establish and administer a 340B program on behalf of a covered entity.

The Wellpartner 340B Access Solution™

For many organizations, the complexity of initiating and administering a 340B program can overwhelm available resources as they grapple with unique operational needs while attempting to offer a service that is beyond the capabilities they currently possess. Many organizations may be reluctant to undertake the effort to establish a 340B program even as they understand the value this program offers to the organization and its patients.

Alternatives are available to organizations that cannot commit the resources and program dollars to create an internal 340B pharmacy solution. For these organizations, Wellpartner has developed the 340B Access Solution, an innovative Contracted Pharmacy fulfillment solution for the 340B Program.

Wellpartner's 340B Access Solution removes the entity's burden of developing and controlling a pharmacy program and allows scarce administration resources to focus on the entity's core mission. Wellpartner's 340B professionals administer the Contracted Pharmacy solution on behalf of the clinic. The 340B Access Solution reduces or eliminates many of the issues or concerns related to administering the program's demanding requirements. In addition, the 340B Access Solution creates an opportunity for qualified entities to generate program revenue that can offset their indigent care initiatives.

The Wellpartner 340B Access Solution offers entities a range of options for managing a 340B program, providing a highly customizable platform for the development and implementation of Contracted Pharmacy services that are unique to an entity's specific needs.

Each entity possesses a unique operating environment and requires an appropriate pharmacy structure that is based on the operational, demographic and financial characteristics of the organization. The 340B Access Solution allows entities to select a specific implementation option that can be designed to ensure the lowest start-up and administrative costs to the entity, while increasing access and ensuring consistent and high quality service for its patients. In addition, with the flexibility of the 340B Access Solution, each program is designed around maximizing the potential of the 340B program, while reducing the resources necessary from the entity to establish, administer and manage the 340B Contract Pharmacy option.

The following discusses implementation alternatives for covered entities who elect to manage their 340B program using the 340B Access Solution from Wellpartner.

Wellpartner Contract Pharmacy Option

With the Contract Pharmacy option of the 340B Access Solution, Wellpartner contracts with the entity to provide Contract Pharmacy services on behalf of the entity through a traditional one-to-one pharmacy - clinic relationship. This approach is consistent with the HRSA published guidelines authorizing a Contract Pharmacy arrangement.

For many organizations, a Contract Pharmacy approach is always the first step towards establishing more robust pharmacy services. It is ideal for smaller clinics or rural entities.

Wellpartner's Contract Pharmacy option minimizes the up-front financial and resource commitment required by entities, and can allow an organization to maximize the revenue potential that is available through the 340B program.

Wellpartner will administer a Contract Pharmacy option for an entity by directing patients with "chronic" prescriptions to mail order, and patients with "acute" prescriptions to either the clinic dispensary or to a retail pharmacy for fulfillment. Given that less than 20% of all prescriptions generated through a typical 340B-eligible entity are for "acute" medications, and that those prescriptions tend to be for low-cost antibiotics that – in most cases – are available less expensive through a retail pharmacy than through a 340B pharmacy, Wellpartner believes that this option is the most effective starting point for creating 340B pharmacy services for an entity's patients.

Wellpartner's Contract Pharmacy option includes the following standard components:

- **Program Administration** – The complexity of the 340B program requires that the entity ensures it takes several important and required actions to guarantee it can administer compliance with both the spirit and the letter of the 340B statute.

  Wellpartner's Contract Pharmacy option establishes a standardized enrollment and processing method that ensures that each prerequisite step required to establish 340B capability, from completing registration with the Office of Pharmacy Affairs to contracting with a wholesale drug distributor for 340B medications, to filing the pharmacy audit, is completed prior to commencing dispensing operations.

- **Pharmacy Benefit Administration (PBA)** – As has been reviewed earlier in this Primer, a successful 340B Contract Pharmacy must be able to perform patient eligibility, claims management and reporting on the prescriptions filled through the Contract Pharmacy facility. Wellpartner's Contract Pharmacy option applies its sophisticated data systems to ensure the proper administration of the entity's 340B program. These systems include

enrollment and prescription validation, site and entity verification, provider and prescription capture, and the administration of the many other data elements necessary for the successful implementation and administration of a 340B pharmacy program. Standardized and ad-hoc reporting capability are available to the entity so it can meet HRSA guidelines for program auditability.

- **Preferred Drug List (PDL) Management** – By restricting the number of medications supported by an entity, a 340B program can reduce the number of supported NDCs and create an opportunity to purchase medications in larger quantities and receive deeper discounts. Wellpartner's Contract Pharmacy option includes resources that assist entities with establishing a Preferred Drug List (PDL).

  Wellpartner works with the entity to develop a PDL that identifies both the lowest cost and the best value medications per class and matches these medications against the formularies of an entity's primary payors. This information is mapped to ensure the number of supported products is limited in order to maximize cost savings for the entity.

  The method used by Wellpartner to assist entities with developing their PDL's is compliant with Joint Commission standards, allowing an easier inspection by JCAHO inspectors.

- **Training of Staff and Providers** – As part of an implementation process, Wellpartner provides comprehensive training and education to all providers and staff in the entity's service delivery sites. Training includes modules ranging from administration and operation of the 340B program to the Preferred Drug List.

- **Patient and Community Education** – A successful 340B pharmacy program depends on involving qualified patients in the 340B program and capturing eligible prescriptions. Wellpartner's 340B Access Solution Contract Pharmacy Option provides an extensive communication, education and awareness program directed at patients, referral providers and agencies, and the community as a whole about the program and the benefits that accrue to individuals and to the community as a result of the program.

- **Distributor Administration and Oversight** – In order for a qualified entity to begin using 340B program prices it must establish a pharmaceutical wholesale distribution agreement. Wellpartner's 340B Access Solution helps organizations establish this capability by including wholesaler agreement options and steps required to set up the whole saler relationship under a "bill to, ship to" arrangement. Wellpartner manages the entity's relationship with the pharmaceutical wholesaler to ensure proper pricing and deliv ery. In addition, Wellpartner

negotiates with each wholesaler to receive additional discounts on administrative fees for the entity.

- **Third Party Capture** – An effectively managed 340B program will enable an entity to process all prescriptions in order to maximize the capture rate of reimbursements available through third-party payors. Wellpartner's 340B Access Solution Contract Pharmacy Option coordinates with the entity to maximize the revenue generated by the capture of prescriptions for patients with insurance coverage. Wellpartner recognizes that this revenue can underwrite the cost of the pharmacy program to the entity's subsidized patient populations. Wellpartner's pharmacy program is designed to achieve a maximum number of qualified patients who utilize the 340B program.

Contracted Network Administration Solution

Another implementation option that is available with Wellpartner's 340B Access Solution is the Contracted Network Administration Option. This option builds on the Contract Pharmacy arrangement where Wellpartner develops and administers a network of contracted retail pharmacies on behalf of an entity under the auspices of an Alternative Method Demonstration Project (AMDP) waiver.

The AMDP waiver allows an entity to escape the restrictions of a "one-to-one" Contracted Pharmacy arrangement and provide 340B program services across a network of contracted pharmacies. Wellpartner has reviewed this model with representatives of the Office of Pharmacy Affairs and received strong encouragement to develop and deploy it. It is believed that by using this model, an entity can significantly increase access to 340B medications and minimize the level of risk associated with administering a program across multiple contract and internal pharmacies.

In addition to the services described in Wellpartner's Contract Pharmacy Option, the Network Administration Option includes the following components:

- **Network Participant Selection and Contracting** – A key component of this option is to establish broad access to 340B patients. Using prior-use patterns supplied by an entity, Wellpartner will identify, educate, and contract with retail pharmacies that are within geographic proximity to the entity to create the entity's 340B pharmacy network. This will establish a number of fulfillment locations that may be used by qualified patients of the entity to fill the prescriptions using 340B program prices.

- **Network Administration** – To manage the pharmacy network for the entity and protect against "Diversion" and "Double-Dipping" Wellpartner's Contracted Network Administration Option will have pharmacies in the 340B network subcontract to Wellpartner. Wellpartner will control the

replenishment, reporting, and adjudication of 340B prescriptions at these pharmacies. This administration feature creates a turnkey 340B network solution for the entity, and reduces the burden of administering a contract pharmacy relationship to a single contractor while significantly increasing pharmacy access.

- **Administration and Application for the AMDP Waiver** – The Contracted Network Administration Option requires OPA waiver approval via an Alternative Method Demonstration Project (AMDP). With this program option, Wellpartner will work with the entity to write the waiver application, and will administer the waiver request on behalf of the entity.

- **Multi-Entity Network Services** – Wellpartner's Contracted Network Administration Option includes an option to administer a network across multiple qualified entities, creating a de-facto open 340B network for the entire safety-net system in a geographic area.

  Utilizing specialized reporting tools, Wellpartner has the ability to accurately report on utilization in near realtime basis, providing audit and reconciliation at the prescription level for each pharmacy and entity in the network, thus allowing for a credible network to be established.

Expansion Efforts

Appropriately applied and supported, the 340B program represents an outstanding vehicle for entities to increase access to lower cost medications while decreasing prescription drug expenses for the entity's patients. Additionally, at its widest application, the 340B program can become an important and much valued source of revenue for the entity. While there have been recent efforts to deploy new 340B programs, with some implementations focused on maximizing the revenue potential of the 340B program for the entity, these attempts have been limited in scope and duration.

There are a broad number of available options that an experienced 340B program administrator can deploy. Wellpartner's team of 340B professionals is available to work with clients who are interested in exploring these 340B expansion possibilities. Expansion opportunities include:

Fee-for-Service Medicaid Agreements
One of the restrictions placed upon dispensing 340B medications to an entity's patients is that the entity cannot bill Fee-for-Service Medicaid at the normal retail rate, as this will create an instance of "Double-Dipping." As the reader may recall, "Double Dipping" occurs when a State Medicaid agency requests a rebate on a medication that was purchased through the 340B program. HRSA requires that any entity that deploys a 340B program must demonstrate that it can avoid this occurrence.

This requirement can be problematic for many entities as a large percentage of the patients that use covered entities

are insured through Fee-for-Service Medicaid. HRSA allows Fee-for-Service medications to be adjudicated through Medicaid in any fashion that is allowed by State agreement and that does not allow for a Medicaid rebate to be requested. One option that many entities explore is to notify the State Medicaid authority that claims will be submitted using the 340B program so the State can avoid applying for rebates on any prescriptions adjudicated through the qualified entity.

Typically, States require the entity to submit a Fee-for-Service prescription claim for reimbursement at acquisition price, plus the State's then current Medicaid dispensing fee. While this option is allowed by HRSA, many entities often find the reimbursement for processing a Fee-for-Service claim insufficient to cover it's costs.

One alternative strategy advocated by Wellpartner to avoid the potential for "Double Dipping" and establish a fair reimbursement for a submitted 340B claim is the creation of an alternative pricing structure to ensure the viability of dispensing 340B medications to Fee-for-Service Medicaid members. Such a strategy can be a win-win situation, as the price the State pays is usually lower than their net of Medicaid rebate price, and the clinic does not have to contend with carving Fee-for-Service Medicaid members out of their pharmacy program or losing money each time they fill a Fee-for-Service Medicaid prescription.

The following identifies several examples where State Medicaid agencies have agreed to modify reimbursements for 340B prescription drug claims.

The most prevalent reimbursement method used today is referred to as the "Actual Acquisition Cost (AAC) Plus" Model. Using the AAC Plus model the entity is reimbursed using a formula based on the AAC – the 340B cost to the entity – plus an enhanced dispensing fee.

Another example is the "Average Wholesale Price (AWP) Minus" Model. With the AWP Minus model the entity is reimbursed using a preset formula based on the product's Average Wholesale Price (AWP) – an industry pricing benchmark – minus a predetermined percentage, usually 30 to 35 percent, plus the standard Medicaid dispensing fee.

A third and final model is the "Blended Model". This model reimburses an entity at either an "AAC Plus" or "AWP Minus" rate, depending upon a prearranged pricing schedule and listing of covered medications.

Each of these models has specific benefits and drawbacks. Each alternative should be examined to understand which is most appropriate for the entity and State Medicaid agency program.

Savings Share Arrangement

An ever increasing number of Medicaid lives are becoming enrolled in Managed Medicaid. As a consequence, there is a increasing number of Managed Medicaid patients who are now treated at covered entities.

Using the 340B program, prescriptions for Managed Medicaid patients treated at covered entities can be filled at the standard payor retail reimbursement rate. The entity will realize an economic gain when the payor pays the adjudicated claim. It is not uncommon for the entity to realize revenues equaling 35 percent of the cost of the drug. However, while this revenue is definitely useful to any entity, a more substantial and significant revenue stream may be available if the entity contracted with the Medicaid Managed Care payor and agreed to share the savings in exchange for the payor limiting the patients' pharmacy network to the covered entity's pharmacy network.

The mechanics leading to an agreement to share savings on adjudicated Medicaid Managed Care claims are not complex. While Fee-for-Service Medicaid recipients may be allowed Freedom of Choice, Medicaid Managed Care recipients are, through the State 1915(b) waiver and resulting enrollment into a Medicaid Managed Care health plan, allowed to be restricted into assigned pharmacy networks. This can produce an opportunity for a Medicaid Managed Care organization to realize per member, per month savings on prescription drugs for members it directs into its restricted pharmacy network. This savings, and the resulting additional revenue to the entity, creates the opportunity for these organizations to align and develop a savings share agreement that can result in a business benefit to each organization.

Similarly, eligibility for coverage on 340B medication that is prescribed to qualified patients that are referred to non-entity providers is allowed when there is a contractual relationship between the entity and the non-entity provider. An example is in a managed care arrangement where a referral is generated by the entity. If the patient's Primary Care Provider is employed by the covered entity and the patient is a patient of the covered entity, the patient's prescriptions generated by outside specialists generally are covered under the 340B program (some exceptions exist). In this example, a savings share arrangement can be developed where the managed care plan has the opportunity to save a significant amount of money while the covered entity has an opportunity to capture additional 340B prescriptions and revenue for prescriptions written by providers that have been referred by the entity.

New Populations

An important criteria for 340B eligibility is that a patient must meet the definition of a qualified patient (as defined by statute) of the covered entity. Recently, eligibility to participate in the 340B program has been extended to include new patient populations that previously had not been excluded from participation in the 340B program. Some of these recent enhancements include:

1. **Prisoner inmate populations** - The State of Texas recently contracted with the University of Texas Medical Branch (a 340B covered entity) to provide medical

care to prisoners housed by the Texas Department of Corrections. By so doing, Texas prison inmates became patients of the covered entity and were therefore eligible for low-cost 340B medications.

2. **Nursing Home Residents** – A Long Term Care (LTC) facility in New York State recently contracted with a Federally Qualified Health Center (FQHC) to provide primary care services to LTC residents. This contract established the LTC residents as patients of the FQHC, and therefore eligible for 340B pricing.

3. **Union Employees** – It was recently proposed that a FQHC in New York State open a satellite service delivery site on the docks of a ship yard in New York. The FQHC would staff the facility, and the union would direct its members to the clinic. These members would then become patients of the FQHC and, again, become qualified to receive 340B medications. This particular proposal is still under consideration.

Benefits of the Wellpartner 340B Access Solution

Wellpartner's 340B Access Solution enables increased access to 340B medications across multiple service delivery sites while centralizing control for a clinic's 340B program.

Furthermore, the program represents an opportunity to reduce or eliminate many of the challenges inherent with 340B Contract Pharmacy programs while simultaneously creating an opportunity for qualified entities to generate program revenues that offset their indigent care initiatives.

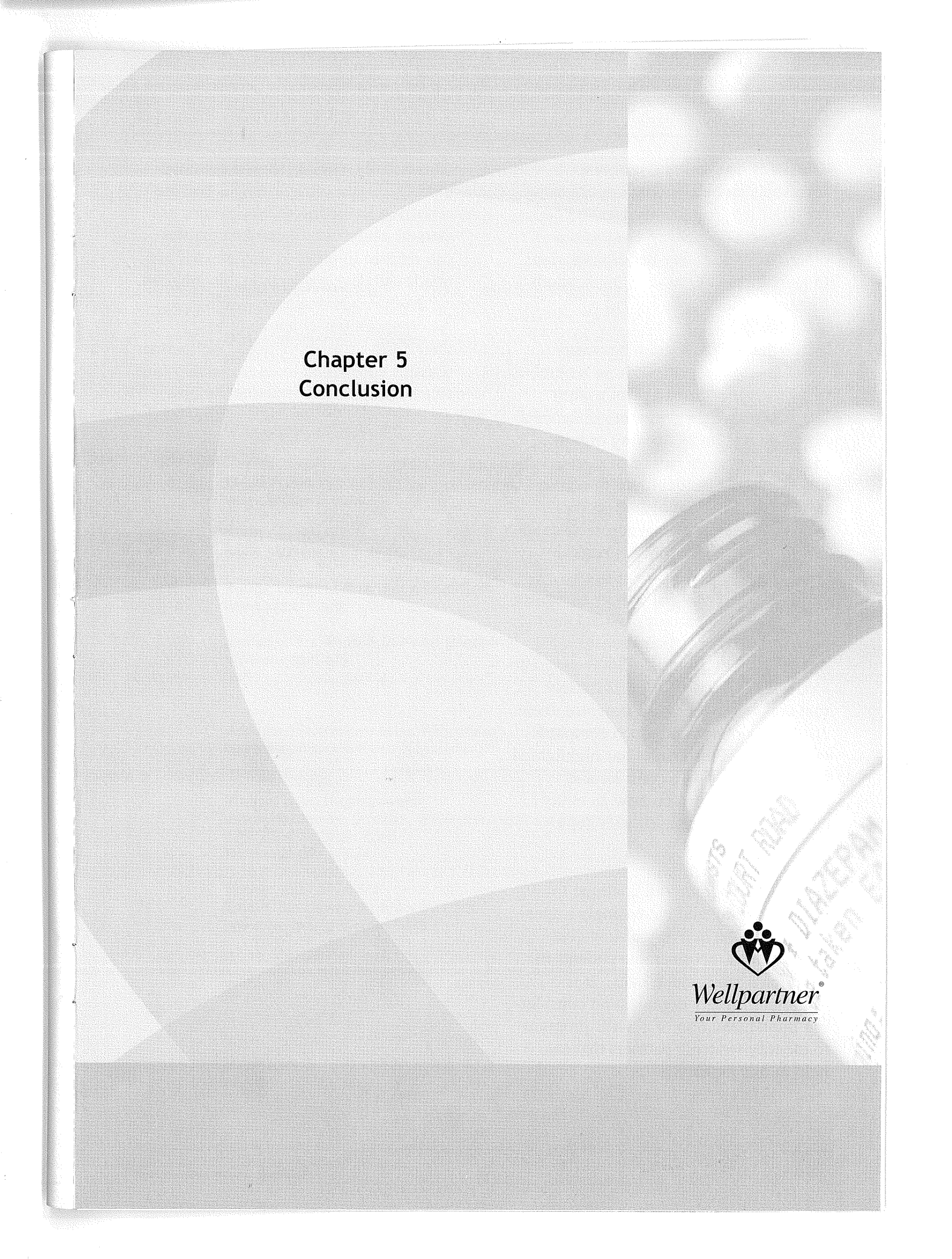
The following summarizes some of the benefits that can accrue to a covered entity that elects to use either of Wellpartner 340B Access Solution options (either Contract Pharmacy or Contracted Network Administration) for its 340B program.

- **Turn key program that is highly Customizable** – The Wellpartner 340B Access Solution is a turn-key program that provides clients with a high degree of flexibility to address the specific design and performance requirements of the client. Whether the client wishes to start by implementing a Contract Pharmacy solution, or a more complex AMDP network proposal, Wellpartner provides the tools and the consulting resource, as well as overall program management resource, to ensure the entity's design will meet the overall program objectives.

- **No Up Front Expense** – Because all of Wellpartner's pharmacy operations perform under a replenishment model, there are no up-front pharmacy or implementation expenses for the entity. In fact, the entity only pays for what is dispensed as it occurs.

- **Potential for Revenue Generation** – Wellpartner provides the entity with our experience at maximizing revenue generation from third party payers and State Medicaid programs. This revenue can be used to support the core mission of the entity, and to expand medication access for subsidized patient populations.

Chapter 5
Conclusion



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The 340B drug pricing program represents an outstanding opportunity for qualified Community Health Clinics, Disproportionate Share Hospitals and other qualified safety-net organizations to gain access to low-cost medications for their patients.

While the 340B program has many benefits, covered entities have a number of options available to them as they begin to plan their program implementations. A solid understanding of how the 340B program can be implemented, and how it can be deployed to deliver maximum value to covered entities while providing optimal access to qualified patients of the entity is critical.

Wellpartner developed this 340B Primer to help covered entities evaluate their program alternatives and consider options as they plan their 340B program strategies. Clearly, for organizations that are new to the 340B program, there are many options and much complexity to consider. This Primer has highlighted the primary items to consider and offered suggestions on how an entity can best advantage itself as it deploys its 340B strategy.

The 340B program will continue to play a growing and increasingly important role in the delivery of low-cost prescriptions to vulnerable patients in America's safety-net clinics. It is important for any organization considering implementation of a 340B program to identify strategic partners that can help in this journey.

Additionally, entities should continue to keep abreast of the changes that are occurring in this field. Wellpartner has created a reference index that entities can refer to in order to stay abreast of trends and developments in this program.

As organizations continue to assess their 340B program options, Wellpartner remains committed to its leadership role helping clients evaluate the best options available for a successful 340B program that meets the cost, quality and access requirements of safety-net organizations.

Appendix - Reference Information

Resources

Additional information about the 340B program can be found at the following resources:

Wellpartner, Inc
www.wellpartner.com/340B

Office of Pharmacy Affairs (OPA)
www.hrsa.gov/odpp

Pharmacy Services Support Center
(Offers free consultations regarding 340B services)
http://pssc.aphanet.org

Healthcare Purchasing Partners International
(340B Prime Vendor)
www.340bpvp.com

340B Coalition
www.340Bcoalition.org

Public Hospital Pharmacy Coalition
www.phpcrx.org

Medicine for People in Need (Medpin)
www.medpin.org

Additional information about Wellpartner's 340B program and 340B Access Solution is available at:

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State of California Department of Consumer Affairs

Memorandum

To: **Licensing Committee** **Date: Sept. 7, 2006**

From: **Board of Pharmacy – Virginia Herold**

Subject: **Restrictions on the Transfer of California Pharmacist Licenses to Other States**

According to a survey done by the NABP last year, 26 states will not accept a North American Pharmacist Licensure Examination (NAPLEX) score if the applicant initially earned that score from being qualified to take the examination by California, and after passing the exam, later applied to become licensed as a pharmacist in these states (see attached).

There is a process by which an applicant who has not yet taken the NAPLEX may ask that his or her NAPLEX score be sent to multiple states. However, not all candidates do this before taking this exam, or discover later that they wish to become licensed as a pharmacist in another state. If the latter occurs, a license transfer is required (which essentially is a transfer of the NAPLEX score and licensure verification) to the new state. The applicant is still required to meet any additional licensure requirements in the new state (e.g., pass the Multistate Pharmacist Jurisprudence Examination for that state)

So for those applicants who apply to California as the primary state to become licensed as a pharmacist, they may have difficulty (or be denied the ability) to use the NAPLEX score later to qualify for licensure in another state and thus have to retake the NAPLEX at some point in the future.

California will allow any applicant to transfer a NAPLEX score to California if the score was earned after January 1, 2004 (which is specified in Business and Professions Code section 4200).

At the July 2006 Board Meeting, the board directed that staff to contact each state that would not accept the NAPLEX score from California to determine why. Staff has not yet initiated this telephone interview with each state that will not accept California scores, but has discussed the issue with the NABP.

Staff at the NABP believe that there are at least two explanations:

1. California's acceptance of NAPLEX scores earned only after January 1, 2004 may be part of the explanation. This is similar to a problem that Florida has, where a number of states will not accept NAPLEX scores from Florida which requires a NAPLEX score to have been earned in the last 12 years.
2. Misunderstanding of what California requires – thinking that California still requires passage of the old California licensure exam, or do not realize the

specifics that California will accept scores from their pharmacists if earned before January 1, 2004.

Before the next Licensing Committee Meeting, staff will conduct one-on-one interviews with the executive officer or other designated staff for those states that will not accept California-earned NAPLEX scores.

The NABP believes that education about California's requirements in such discussions may help resolve the problem.

National Association of Boards of Pharmacy

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TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Mary A. Dickson, Associate Executive Director

DATE: March 31, 2006

RE: State Restrictions for Licensure Transfer

As a follow-up to the Licensure Transfer Process Memo sent on March 10, 2006, NABP would like to take this opportunity to share restrictions that apply to an applicant when reciprocating to a jurisdiction using a particular license. Most states **do** reciprocate with each other; however, several states do not allow an applicant to transfer when using a particular license for the basis of transfer.

Currently the following 17 jurisdictions do **not** allow transfer when using a **Florida** license for the basis of transfer:

Alabama	Louisiana	Oregon
Arkansas	Minnesota	Tennessee
Connecticut	Nevada	West Virginia
Georgia	North Carolina	Wyoming
Hawaii	Ohio	
Idaho	Oklahoma	

Currently the following 26 jurisdictions do **not** allow transfer when using a **California** license for the basis of transfer:

Alabama	Idaho	Maryland	Oklahoma	West Virginia
Arkansas	Indiana	Mississippi	Pennsylvania	Wyoming
Colorado	Iowa	Montana	Rhode Island	
Connecticut	Kentucky	Nevada	Utah	
District of Columbia	Louisiana	New Jersey	Vermont	
Georgia	Maine	North Carolina	Washington	

With the recent Bylaw change (effective May 23, 2005); licensure transfer applicants will no longer be required to maintain the license that was required by original examination in order to transfer into some jurisdictions. A recent survey conducted by NABP on September 16, 2005, indicates that this is not the case for all jurisdictions.

Currently the following 20 jurisdictions will require licensure transfer applicants to maintain their license by original examination:

Alabama	District of Columbia	Missouri	New York	South Carolina
Alaska	Kentucky	Nevada	North Dakota	South Dakota
Arizona	Louisiana	New Hampshire	Oklahoma	West Virginia
Arkansas	Maine	New Jersey	Oregon	Wyoming

* Please note: not all jurisdictions replied to the survey, and some decisions are pending.

Currently the following 21 jurisdictions will not require licensure transfer applicants to maintain their license by original examination, but the licensure transfer applicant must have a license in good standing from a member board of pharmacy and transferred their license through the NABP Clearinghouse:

California	Illinois	Massachusetts	Nebraska	Texas	Wisconsin
Delaware	Indiana	Minnesota	Ohio	Utah	
Georgia	Iowa	Mississippi	Puerto Rico	Vermont	
Idaho	Maryland	Montana	Rhode Island	Virginia	

* Please note: not all jurisdictions replied to the survey, and some decisions are pending.

We hope you find this information helpful to understanding the license transfer restrictions posed on licensure transfer applicants. If you have any questions about the restrictions, please contact me via phone at 847/391-4400 or 1-800/774-6227 or via e-mail at mdickson@nabp.net. Thank you.

cc: NABP Executive Committee
Carmen A. Catizone, Executive Director/Secretary

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

To: Licensing Committee Date: September 7, 2006

From: Board of Pharmacy

Subject: Certification Process for Foreign-Educated Pharmacists and the Elimination of the Administration of Test of Spoken English (TSE)

Background

California law requires foreign educated pharmacy graduates to be certified by the Foreign Graduate Examination Committee (FPGEC) to satisfy the educational equivalency requirement with that of domestic pharmacy school graduates contained in California Business and Professions Code section 4200. The FPGEC is a subdivision of the National Association of Boards of Pharmacy.

In 1997, the FPGEC began requiring a Test of Spoken English (TSE) score of 50 as a component of certification. However, since 1991 California has required foreign-educated pharmacists to pass the TSE with a specific score.

Recognizing the duplication of this requirement once the FPGEC required the TSE, California law was amended in the late 1990s to require candidates who became FPGEC certified before January 1,1998, to continue to provide a passing TSE score to the board. Those certified after 1998 were required to pass the TSE as a component to becoming FPGEC certified, but were not required to retake the TSE specifically for California.

Transition to Test of English as a Foreign Language Internet-based Test (TOEFL iBT)

The TSE is administered by Educational Testing Services (ETS). Effective June 2006, ETS announced the discontinuation of TSE and transition to TOEFL iBT.

According to ETS, TOEFL iBT tests all four language skills that are important for effective communication: speaking, listening, reading, and writing. The test helps students demonstrate that they have the English skills needed for success.

The original TOEFL iBT introduction schedule stated that the TSE would be discontinued as a stand-alone test as of July 2006. However, because TOEFL iBT will now be introduced only in locations where there is sufficient testing capacity, ETS will administer the TSE test on August 19, October 14, and November 18, 2006, and January 13 and March 9, 2007, in locations outside the United States and Canada.

The FPGEC has begun accepting the TOEFL iBT examination in place of the TSE as a required component for FPGEC certification.

However, in recent months, the board has heard from several applicants who were certified by the FPGEC before the TSE requirement was a component of the certification process (i.e., before 1998), and who have not been able to pass the TSE. These applicants are expressing concern about how they will qualify to take the pharmacist licensure examination in California if the TSE is no longer administered.

The FPGEC will now recertify those candidates who have been certified before 1998 after they complete and pass the TOEFL iBT examination. This will provide a resolution for those candidates who cannot achieve an acceptable passing score on the soon-to-be discontinued TSE.

State of California Department of Consumer Affairs

Memorandum

To: **Licensing Committee** **Date: Sept. 7, 2006**

From: **Board of Pharmacy – Virginia Herold**

Subject: **Update on Assembly Bill 595 and US District Court Opinion Supports Compounding by Pharmacies**

In 2004, the Licensing Committee formed a Workgroup on Compounding to evaluate whether a distinction could be made between compounding by a pharmacy and manufacturing operations that are performed by a drug manufacturer. This workgroup formed in part due to a request from the Department of Health Services seeking the board's determination of when a pharmacy is compounding, and when a pharmacy has become a drug manufacturer, and thus subject to licensure by the Department of Health Services or federal Food and Drug Administration.

This workgroup was comprised of staff from the board, from the Department of Health Services, compounding pharmacies, pharmacy associations and others. Over the course of 2004, the group met quarterly. However, the group was unable to develop standards to distinguish when a pharmacy has crossed from compounding into manufacturing, and thus would be subject to licensure as a manufacturer. Instead, a legislative proposal and draft regulations were developed to establish standards for pharmacies that compound medication, leaving to the Department of Health Services or FDA the determination of when a pharmacy is manufacturing.

In 2005, the board sponsored the proposed statutory provisions in legislation introduced as AB 595 (Negrete-McLeod). In August 2005, AB 595 was on the floor of the Senate when opposition from the Department of Health Services was formally announced. During 2006, the board and interested stakeholders worked to remove the Department of Health Services' opposition, but we were never successful. The Department of Health Services remained opposed to various provisions, but primarily the provisions that would have allowed a pharmacy to contract with another pharmacy to compound medication for the first pharmacy. Amendments desired by Health Services would have required a separate pharmacy license and annual inspections for pharmacies that compound medication for other pharmacies.

And at the very end of the 2006 legislative session, after months of effort to remove or reduce DHS' opposition, amendments to AB 595 appeared in print that were aimed at reducing DHS' opposition. However, Kaiser, CPhA and Grandpa's Pharmacy came out in opposition to these amendments. Whereas former Executive Officer Patricia Harris feels that these amendments had been agreed upon earlier, the bill was dropped at the end of the session (DHS never removed its opposition).

Very recently, after the board dropped AB 595, the board obtained a court decision restricting the FDA's regulation of pharmacy compounding based on a lawsuit filed in Texas. A copy of this decision is attached.

At this meeting, Deputy Attorney General Joshua Room will discuss the meaning of this decision to pharmacy compounding.

Attachments: AB 594
US District Court Western District of Texas

AMENDED IN SENATE AUGUST 24, 2006

AMENDED IN SENATE MAY 26, 2005

AMENDED IN ASSEMBLY APRIL 18, 2005

AMENDED IN ASSEMBLY MARCH 29, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 595

Introduced by Assembly Member Negrete McLeod

February 17, 2005

An act to amend Section ~~4051~~ *4033* of, to add Section 4019.5 to, ~~to repeal Section 4033 of,~~ and to repeal and add Section 4123 of, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 595, as amended, Negrete McLeod. Pharmacy: compounding of prescription drugs.

Existing law, the Pharmacy Law, provides for the licensing and regulation by the California State Board of Pharmacy of pharmacists, pharmacies, and other related practices and makes a violation of that law a crime. The Pharmacy Law defines various terms for its purposes, including *"manufacturer" and provides specified exceptions from the definition of a* "manufacturer."

This bill would ~~delete~~ *revise* the definition of manufacturer *to except only pharmacies that compound or otherwise manufacture on the immediate premises where the drug or device is sold to the ultimate consumer and pharmacies compounding pursuant to a contract with another pharmacy, and would except those pharmacies from registration or licensing as a manufacturer or otherwise complying*

with federal or state laws regulating manufacturers, unless otherwise determined by a federal or state agency regulating manufacturers. The bill would define compounding of a prescription drug for the purposes of the Pharmacy Law and would ~~make other related changes in that regard~~ *impose specified requirements on dispensing of compounded drugs. The bill would authorize a pharmacy to contract with another pharmacy to compound products on behalf of its patients, subject to specified requirements. The bill would also impose requirements with respect to recalling a compounded drug product.* Because the bill would specify requirements for compounded drug products under the Pharmacy Law, *the violation of which would be a crime,* it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4019.5 is added to the Business and Professions Code, to read:

4019.5. (a) "Compounding" means any of the following activities occurring in a pharmacy pursuant to a prescription:

(1) Altering the dosage form or delivery system of a drug.

(2) Altering the strength of a drug.

(3) Combining components or active ingredients.

(4) Preparing a drug product from bulk chemicals.

(b) "Compounding" shall not include the reconstitution of a drug pursuant to the manufacturer's direction for oral, rectal, or topical administration.

~~SEC. 2. Section 4033 of the Business and Professions Code is repealed.~~

~~SEC. 3. Section 4051 of the Business and Professions Code is amended to read:~~

~~4051. (a) Except as otherwise provided in this chapter, it is unlawful for any person to compound, furnish, sell, or dispense~~

~~any dangerous drug or dangerous device, or to dispense or compound any prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist under this chapter.~~

~~(b) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription, pursuant to Section 4052, and otherwise provide clinical advice or information or patient consultation if all of the following conditions are met:~~

~~(1) The clinical advice or information or patient consultation is provided to a health care professional or to a patient.~~

~~(2) The pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice.~~

~~(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.~~

SEC. 2. Section 4033 of the Business and Professions Code is amended to read:

4033. ~~(a)~~ "Manufacturer" means and includes every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer *or a pharmacy compounding pursuant to a contract as provided in Section 4123. Any excepted compounding pharmacy shall not be required to register as a manufacturer with, or seek licensure by, any federal or state agency regulating manufacturers or otherwise comply with any federal or state law regarding manufacturers, absent a determination by a federal or state agency regulating manufacturers that the pharmacy must do so. Neither this definition nor any other provision of this chapter shall impair the authority of a federal or state agency regulating manufacturers to apply laws regulating manufacturers to a pharmacy.*

~~(b) Notwithstanding subdivision (a), "manufacturer" shall not mean a pharmacy compounding a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy for the purpose of delivering or administering the drug to the patient or patients named in the prescription, provided that neither the components for the drug nor the drug are compounded, fabricated, packaged, or otherwise prepared prior to receipt of the prescription.~~

~~(c) Notwithstanding subdivision (a), "manufacturer" shall not mean a pharmacy that, at a patient's request, repackages a drug previously dispensed to the patient, or to the patient's agent, pursuant to a prescription.~~

~~SEC. 4.~~

SEC. 3. Section 4123 of the Business and Professions Code is repealed.

~~SEC. 5.~~

SEC. 4. Section 4123 is added to the Business and Professions Code, to read:

4123. (a) A compounded drug product shall only be dispensed or furnished to a patient pursuant to a prescription meeting the requirements of Section 4040.

(b) A compounded drug product shall only be dispensed or furnished to a patient where the prescription has been generated solely within an established professional relationship between the prescriber, patient, and dispensing pharmacy.

(c) A pharmacy may conduct anticipatory compounding of a drug product in limited quantity, as defined by regulation of the board, before receipt of a prescription order for that drug product, where the quantity of each drug product compounded in anticipation of receipt of prescription orders is based on a documented history of receipt of prescription orders generated solely within an established professional relationship between prescribers, patients of the pharmacy, and the pharmacy.

(d) A pharmacy may contract with another pharmacy to compound drug products on behalf of its patients, *provided that all of the following requirements are met:*

(1) Any pharmacy that compounds a drug product for another pharmacy shall report that contractual arrangement to the board. The information shall be reported by the pharmacy performing the compounding services within 30 days of commencing that compounding.

(2) The drug product shall not be compounded prior to receipt of the prescription by the pharmacy doing the compounding.

(3) Both the pharmacist that compounds the drug product and the pharmacist that dispenses or furnishes the compounded drug product to the patient pursuant to a prescription shall have access to and appropriately review the patient's medication profile and other pertinent patient information prior to

compounding and prior to dispensing or furnishing the drug product to the patient.

(4) Both the pharmacy that compounds the drug product and the pharmacy under contract that dispenses or furnishes the compounded drug product to the patient pursuant to a prescription shall maintain complete and adequate records of the required drug therapy review performed by each prior to compounding, dispensing, or furnishing the drug product.

(5) The pharmacy that compounds the drug product shall supply the pharmacy under contract that dispenses or furnishes the compounded drug product to the patient with documentation regarding the compounded drug product sufficient to enable the pharmacist dispensing or furnishing the compounded drug product to the patient to both adequately perform the required drug therapy review and provide consultation to the patient, as required by regulation of the board.

(6) Both the pharmacy that compounds the drug product and the pharmacy under contract that dispenses or furnishes the compounded drug product to the patient shall retain on the licensed premises in a readily retrievable form for a period of three years from the date of creation all records of the required drug utilization review performed by each pharmacy, as well as all documentation regarding the compounded drug product shared between the two pharmacies.

(7) The pharmacy that compounds the drug product and the pharmacy that dispenses or furnishes the compounded drug product to the patient shall both be responsible for ensuring that the prescription has been properly filled and that the compounded drug product has been safely delivered to the patient.

(e) A pharmacy may only base its anticipatory compounding on a documented history of prescription orders received for its own patients or customers, and not those patients or customers of pharmacies with which it has a contractual relationship.

(f) Notwithstanding any other provision of this chapter, a pharmacist may ~~do both of the following:~~

~~(1) Compound a drug product pursuant to a prescription, for delivery to another pharmacy pursuant to a contract for the purpose of dispensing or furnishing the drug product to the~~

~~patient named in the prescription, provided that the drug is not compounded prior to the receipt of the prescription.~~

~~(2) Repackage~~ *repackage* a drug previously dispensed to the patient at the request of the patient or the patient's agent.

(g) A pharmacy shall recall a compounded drug product that is misbranded, adulterated, or has the potential for adverse effects or patient harm with continued use of the drug product. Within two business days of discovery of a drug product that is misbranded, adulterated, or has the potential for adverse effects or patient harm, the pharmacy shall notify the prescriber and patient of the nature of the recall, the problems identified, and any recommended actions to ensure patient safety. Any recall that is initiated by a pharmacy pursuant to this section shall also be reported to the board and to the Food and Drug Branch of the State Department of Health Services within two business days.

~~SEC. 6.~~

SEC. 5. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
MIDLAND-ODESSA DIVISION

MEDICAL CENTER PHARMACY, *et al.*	§	
Plaintiffs	§	
	§	
v.	§	**MO-04-CV-130**
	§	
GONZALES, *et al.*	§	
Defendants	§	

ORDER GRANTING IN PART PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND GRANTING IN PART DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

Before the Court are Plaintiffs' Motion for Summary Judgment, filed March 31, 2006; Defendants' Motion for Summary Judgment, filed March 31, 2006; and numerous responses, replies, and supplemental briefs. On May 25, 2006, the Court held a hearing over the parties' Motions for Summary Judgment. After due consideration, and in accordance with the oral pronouncement made at the hearing, the Court finds the following order shall now enter.

FACTUAL AND PROCEDURAL BACKGROUND

Plaintiffs are a group of ten state-licensed pharmacies that specialize in compounding prescription drugs for humans and non-food animals. Although the Food, Drug and Cosmetic Act ("the Act"), 21 U.S.C. § 301, *et seq.*, does not define the terms compounding or compounded drug, the practice has been generally defined as the process by which "a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360–61 (2002). These hybrid drugs are typically created in the absence of a commercially available drug which would serve a similar purpose, or where a commercially available drug contains ingredients to which the patient is allergic. The practice of compounding drugs from approved ingredients saves time

and money for patients and physicians. Every state legislature has authorized the compounding of drugs, and state governments continue to regulate the practice.

On September 27, 2004, Plaintiffs filed the instant lawsuit challenging the authority of the FDA to regulate compounded drugs and to inspect state-licensed retail pharmacies under the Act. On January 27, 2005, Defendants filed a Motion to Dismiss, seeking dismissal of the case for failure to state a claim upon which relief can be granted. At a hearing on May 23, 2005, this Court denied, without prejudice, Defendants' Motion to Dismiss and both parties engaged in discovery. On February 24, 2006, Plaintiffs' Motion for Leave to File an Amended Complaint was granted. The Amended Complaint sought declaratory and injunctive relief on seven counts. Specifically, Plaintiffs requested (1) declaratory judgment under the new drug definitions found in 21 U.S.C. §§ 321(p)(1) and (v)(1), (2) injunctive relief under the new drug definitions, (3) declaratory judgment under the exemption contained in 21 U.S.C. § 374(a)(1), (4) injunctive relief under the exemption contained in 21 U.S.C. § 374(a)(1), (5) declaratory judgment regarding the FDA's policy that compounding from bulk ingredients for non-food animals is illegal, (6) injunctive relief regarding Compliance Policy Guideline 608.400, and (7) injunctive relief under 21 U.S.C. § 331(f).

Thereafter, on March 31, 2006, Plaintiffs and Defendants filed competing Motions for Summary Judgment. In their Motion for Summary Judgment, Plaintiffs seek:

1. a declaration that drugs compounded by licensed pharmacists are not "new drugs" or "new animal drugs" *per se* under 21 U.S.C. §§ 321(p)(1) and (v)(1);

2. an injunction that prevents the FDA from declaring that compounded drugs are "new drugs" or "new animal drugs" under 21 U.S.C. §§ 321(p)(1) or (v)(1) and therefore subject to the requirements and prohibitions imposed upon such drugs under the Act;

3. an injunction that prevents the FDA from enforcing its position that compounded drugs are "new drugs" or "new animal drugs" under 21 U.S.C. §§ 321(p)(1) or (v)(1) and therefore subject to the requirements and prohibitions imposed upon such drugs under the Act;

4. a declaration that the FDA is prohibited from compelling inspections that exceed the grounds enunciated in the first sentence of 21 U.S.C. § 374(a)(1) of pharmacies like Plaintiffs that comply with the requirements of 21 U.S.C. § 374(a)(2)(A);

5. an injunction that prevents the FDA from engaging in inspections that exceed the subjects enunciated in the first sentence of 21 U.S.C. § 374(a)(1) of pharmacies that are in good standing with their respective State boards of pharmacy and have met the Exemption Criteria;

6. a declaration that Compliance Policy Guideline 608.400 and the Notice are unenforceable;

7. a declaration that the FDA does not have the authority to declare compounding from bulk ingredients for non-food animals illegal;

8. an injunction that prevents the FDA from enforcing its current Compliance Policy Guideline which unilaterally declares that compounding from bulk ingredients for non-food animals is illegal;

9. an order requiring the FDA to rescind the Notice at issue in this case;

10. an order requiring the FDA to publish a copy of the Court's order on its website;

11. an injunction that prevents the FDA from prohibiting Plaintiffs or similarly situated pharmacies from receiving bulk ingredients;

12. an injunction that prevents the FDA from bringing prosecutorial, enforcement or punitive actions against any Plaintiffs for refusing to allow the FDA to conduct inspections exceeding the first sentence of 21 U.S.C. § 374(a)(1) of their pharmacies, pursuant to 21 U.S.C. § 374(a)(2)(A), absent independent evidence from the relevant State boards of pharmacy that Plaintiffs are non-compliant; and

13. any and all other relief, in law or in equity, as may be just.

Plaintiffs filed a Response to Defendants' Motion on April 20, 2006, and Defendants' Reply was filed on April 21, 2006. Thereafter on May 25, 2006, this Court held a hearing over

the Motions for Summary Judgment. At the conclusion of the hearing, the Court orally granted Plaintiffs' Motion for Summary Judgment in part, and took several remaining issues under advisement. After the hearing, both parties filed supplemental briefs, which this Court has duly considered.

STANDARD OF REVIEW

Summary judgment should be granted only where "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." FED. R. CIV. P. 56(c). In this case, Plaintiffs and Defendants represent to the Court that no genuine issues of material fact exist. They both filed Motions for Summary Judgment and agree that adjudication based on the summary judgment motions is proper.

DISCUSSION

In their Motion for Summary Judgment, Plaintiffs argue they are entitled to declaratory and injunctive relief on several grounds, as enumerated above. The Court finds that the requested relief can be grouped into the following topics: (1) Compounded Drugs, (2) Inspections, (3) Compounding from Bulk Ingredients for Non-Food Animals, (4) Compliance Policy Guideline 608.400 and the Notice, and (5) Injunctions. Each topic shall be examined individually below.

(1) Compounded Drugs

Plaintiffs first contend that compounded drugs, prepared by pharmacists in the regular course of their business pursuant to a prescription from a licensed practitioner are not new drugs

under the Act. However, Defendants maintain that compounded drugs fall within the definitions of new drugs found at 21 U.S.C. §§ 321(p)(1) and (v)(1).[1] The new drug definitions state:

> "(p) The term "new drug" means –
>
> (1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof..."

21 U.S.C. § 321(p)(1).

> "(v) The term "new animal drug" means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed, –
>
> (1) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof..."

21 U.S.C. § 321(v)(1). Taken alone, the new drug definitions might seem to indicate that compound drugs fall within their provisions. However, after examining relevant case and

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[1] When reviewing an agency's interpretation of a statute, a court should look to the plain language of the statute and determine whether the agency construction conflicts with the text. *Supreme Beef Processors, Inc. v. United States Dept. of Ag.*, 275 F.3d 432, 438 (5th Cir. 2001) (citing *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984). Then, "[i]f the agency interpretation is not in conflict with the plain language of the statute, deference is due." *Id.* Additionally, "[t]he judiciary is the final authority on issues of statutory construction and must reject administrative constructions which are contrary to clear congressional intent." *Chevron U.S.A.*, 467 U.S. at 843 n. 9. This Court has afforded the appropriate deference to the FDA's interpretation of the statutory provisions at issue in this case. For the reasons contained in this Order, however, this Court rejects the FDA's construction of those statutes.

statutory law, as well as legislative intent, this Court finds that compound drugs are implicitly exempt from the new drug definitions contained in § 321.

a. 21 U.S.C. § 353a

In 1997, Congress enacted the Food and Drug Administration Modernization Act of 1997 ("FDAMA"). In doing so, § 127(a) of FDAMA was codified and added to the Act under 21 U.S.C. § 353a. At the time it was enacted, Section 353a declared:

"a) In general

> Sections 351(a)(2)(B), 352(f)(1), and 355 of this title shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section, and if the compounding –
>
> (1) is by –
>
> (A) a licensed pharmacist in a State licensed pharmacy or a Federal facility, or
>
> (B) a licensed physician,
>
> on the prescription order for such individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or
>
> (2) (A) is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and
>
> (B) is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between –
>
> (I) the licensed pharmacist or licensed physician; and
>
> (ii) (I) such individual patient for whom the prescription order will be provided; or

(II) the physician or other licensed practitioner who will write such prescription order.

(b) Compounded drug

(1) Licensed pharmacist and licensed physician

A drug product may be compounded under subsection (a) of this section if the licensed pharmacist or licensed physician –

(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of Title 21 of the Code of Federal Regulations –

(I) that –

(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or

(III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (d) of this section;

(ii) that are manufactured by an establishment that is registered under section 360 of this title (including a foreign establishment that is registered under section 360(I) of this title); and

(iii) that are accompanied by valid certificates of analysis for each bulk drug substance;

(B) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(C) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective; and

(D) does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.

(2) Definition

For purposes of paragraph (1)(D), the term "essentially a copy of a commercially available drug product" does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product.

(3) Drug product

A drug product may be compounded under subsection (a) only if –

(A) such drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and

(B) such drug product is compounded in a State –

(I) that has entered into a memorandum of understanding with the Secretary which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State; or

(ii) that has not entered into the memorandum of understanding described in clause (I) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician.

The Secretary shall, in consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by the States in complying with subparagraph (B)(I).

(c) Advertising and promotion

A drug may be compounded under subsection (a) of this section only if the pharmacy, licensed pharmacist, or licensed physician does not advertise or promote the compounding of any particular drug, class of drug, or type of drug. The pharmacy, licensed pharmacist, or licensed physician may advertise and promote the compounding service provided by the licensed pharmacist or licensed physician.

(d) Regulations

(1) In general

The Secretary shall issue regulations to implement this section. Before issuing regulations to implement subsections (b)(1)(A)(i)(III), (b)(1)(C), or (b)(3)(A) of this section, the Secretary shall convene and consult an advisory committee on compounding unless the Secretary determines that the issuance of such regulations before consultation is necessary to protect the public health. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopoeia, pharmacy, physician, and consumer organizations, and other experts selected by the Secretary.

(2) Limiting compounding

The Secretary, in consultation with the United States Pharmacopoeia Convention, Incorporated, shall promulgate regulations identifying drug substances that may be used in compounding under subsection (b)(1)(A)(i)(III) of this section for which a monograph does not exist or which are not components of drug products approved by the Secretary. The Secretary shall include in the regulation the criteria for such substances, which shall include historical use, reports in peer reviewed medical literature, or other criteria the Secretary may identify.

(e) Application

This section shall not apply to –

(1) compounded positron emission tomography drugs as defined in section 321(ii) of this title; or

(2) radiopharmaceuticals.

(f) "Compounding" defined

As used in this section, the term "compounding" does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling."

Thus, when enacted, § 353a exempted compounded drugs from the FDA's drug approval process, provided that drug compounders complied with various restrictions. These restrictions included refraining from advertising or promoting certain compounded drugs. *See* 21 U.S.C. §§ 353a(a), (c). After the passage of FDAMA, a group of pharmacies that specialized in compounding filed suit, complaining that the provisions of § 353a that restricted advertising and solicitation violated the free speech guarantee provided by the First Amendment to the United States Constitution. *See W. States Med. Ctr. v. Shalala*, 69 F.Supp.2d 1288 (D. Nev. 1999). The District Court for the District of Nevada found that the relevant provisions did violate the First Amendment, however it severed the remaining portions of the statute. *Id.* On appeal, the Ninth Circuit Court of Appeals affirmed in part and reversed in part, holding that the advertisement and solicitation provisions were unconstitutional, but they were not severable from the remainder of the section. *See W. States Med. Ctr. v. Shalala*, 238 F.3d 1090 (9th Cir. 2001). The United States Supreme Court then granted certiorari, however it only reviewed the free speech issue of the case as the severability issue was not raised before it. *See Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002).

Upon review of the case, the Supreme Court found that subsections (a) and (c) of § 353a did violate the free speech guarantee of the Constitution of the United States. *Id.* However, the Court unequivocally stated that it was not reviewing the Court of Appeals' conclusion regarding severability. *See* 535 U.S. at 360 ("We therefore only address the constitutional question, having

no occasion to review the Court of Appeals' severability determination"); *Id.* at 366 ("Because neither party petitioned for certiorari on the severability issue, we have no occasion to review that portion of the Court of Appeals' decision"). Moreover, the majority's concluding sentence of the opinion declared "we affirm the Court of Appeals' judgment that the speech-related provisions of FDAMA § 127(a) are unconstitutional." *Id.* at 377. The holding of the Supreme Court was limited to adjudging §§ 353a(a) and (c) unconstitutional, and the issue of whether the remainder of the statute was severable was not considered. Thus, the last court to rule on the severability issue was the Ninth Circuit Court of Appeals.

Although the Ninth Circuit ruled that the remaining portions of § 353a were not severable from the provisions regarding solicitation and advertising, this Court is not bound by that determination as "the Fifth Circuit is in no way bound by decisions rendered by other circuits." *United States v. Dawson*, 576 F.2d 656, 659 (5th Cir. 1978). Rather, the opinions of sister circuits are only considered persuasive authority. *Id.* Additionally, this Court is not alone in recognizing that § 353a has not been declared invalid in its entirety by the Supreme Court. *See United States v. Livdahl*, 2005 WL 3970828 at *8 n. 4 (S.D. Fla. 2005) ("This Circuit has not addressed the issue of whether § 353a is invalid in its entirety based on the unconstitutionality of §§ 353a(a) and (c)"). Therefore, because this Court is not bound by the Ninth Circuit's ruling on severability, it shall now consider whether the remaining provisions of § 353a are still intact.

It is well established that "a court should refrain from invalidating more of the statute than is necessary." *Regan v. Time, Inc.*, 468 U.S. 641, 652 (1984)(plurality opinion). If a statute contains provisions that are severable from the unconstitutional portions, a court shall maintain the statute "so far as it is valid." *Id.* When determining if a statute is severable, a court shall examine the statute to see if the constitutionally permissible portions are "fully operative as a

law." *I.N.S. v. Chadha*, 462 U.S. 919, 934 (1983). If the permissible portions are fully operative as law, any offending portions should be severed "[u]nless it is evident that the Legislature would not have enacted those provisions which are within its power, independently of that which is not." *Id.* In making this determination, a court shall evaluate "whether the statute will function in a *manner* consistent with the intent of Congress." *Alaska Airlines v. Brock*, 480 U.S. 678, 685 (1987). Therefore, a court may invalidate an entire statute only if the remaining portions of the statute cannot operate independently or there is clear evidence that Congress would not have enacted the statute without the portions that have been declared unconstitutional.

However, if Congress has explicitly provided for severance through the inclusion of a severability clause, "the inquiry is eased." *Id.* at 686. The inclusion of a severability clause "creates a presumption that Congress did not intend the validity of the statute in question to depend on the validity of the constitutionally offensive provision." *Id.* (citations omitted). "This presumption may be overcome only by 'strong evidence' that Congress would not have enacted the law without the invalidated portions of the statute." *Koog v. United States*, 79 F.3d 452, 462 (5th Cir. 1996) (citing *Alaska Airlines*, 480 U.S. at 686).

In the Act, Congress included a severability clause which clearly dictates the course of action should part of a statute contained therein be declared unconstitutional. Found in § 391, the severability clause states: "[i]f any provision of this chapter is declared unconstitutional, or the applicability thereof to any person or circumstances is held invalid, the constitutionality of the remainder of the chapter and the applicability thereof to other persons and circumstances shall not be affected thereby." *See* 21 U.S.C. § 391. The existence of this clause creates a presumption that Congress intended the rest of a provision contained within the Act would remain valid if a portion was declared unconstitutional.

In making its determination, the Ninth Circuit relied heavily on the legislative history attached to the passage of FDAMA. However, in the Fifth Circuit, a court "cannot search legislative history for congressional intent unless [it finds] the statute unclear or ambiguous." *In re Abott Labs.*, 51 F.3d 524, 528 (5th Cir. 1995); *see also United States v. Missouri Pac. R.R. Co.*, 278 U.S. 269, 278 (1929) ("[W]here the language of an enactment is clear, and construction according to its terms does not lead to absurd or impracticable consequences, the words employed are to be taken as the final expression of the meaning intended."). In this case, the language of the severability statute contained in the Act is clear and unambiguous. Therefore, the Court finds that the severability statute must be given its full effect. The offending portions of § 353a are severed and the remainder of the statute remains in full effect.[2]

After subsection (a) and (c) of § 353a are severed, the remaining provisions of the section demonstrate that Congress intended to declare that compounding is an approved and legal practice. The existence of the remaining portions of the statute permit pharmacies to compound drugs. Because pharmacies are permitted to compound, this Court finds that any drugs created by the compounding process are authorized under § 353a and are therefore implicitly exempt from the new drug approval process and the definitions found in 21 U.S.C. § 321 (p)(1) and (v)(1).

However, the Court notes that the FDA has raised valid concerns regarding pharmacies that claim to be compounding but in actuality are manufacturing drugs. Thus, pursuant to guidance from the FDA found in Compliance Policy Guideline 460.200, discussed in more detail *infra*, the Court finds that the exemption for compounded drugs from the new drug definition is

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[2] Even assuming *arguendo* that the severability provision in the Act does not control in this case, the Court finds after reviewing the relevant legislative history that its decision would not be altered. The legislative history tied to the passage of § 353a does not overcome the presumption of severability that is created through the existence of the severability clause.

limited to compounds which are made in reasonable quantities upon receipt of a valid prescription for an individual patient from a licensed practitioner. Drugs that are compounded in large quantities before a prescription is received from a doctor do not fall within the narrow exemption this Court finds exists.

b. *Western States*

Although this Court has not been presented with a single case which explicitly declares that compounding is either legal or prohibited, the Supreme Court recognized the practice of compounding in *Western States*. Therein, the Court outlined the history of compounding and acknowledged the importance of the process. Specifically, the Court stated:

> "The Government also has an important interest, however, in permitting the continuation of the practice of compounding so that patients with particular needs may obtain medications suited to those needs. And it would not make sense to require compounded drugs created to meet the unique needs of patients to undergo the testing required for the new drug approval process. Pharmacists do not make enough money from small-scale compounding to make safety and efficacy testing of their compounded drugs economically feasible, so *requiring such testing would force pharmacists to stop providing compounded drugs*."

W. States, 535 U.S. at 369-70 (emphasis added). The language of this case expresses the Supreme Court's acknowledgment of the importance of compounding and the reasons why it is not practical for compounded drugs to be subject to the new drug approval process.

The Court finds that the language of *Western States* demonstrates that compounding is a process that has been approved by the Supreme Court, albeit in dicta. Further, this Court finds that if compounding is a legal activity, then any drugs created through the compounding process must be exempt from the new drug definitions found in the Act. If compounded drugs are not exempt, the drugs would be required to undergo the new drug approval process, which as recognized by the Supreme Court in *Western States*, is not a viable option for compounded drugs.

c. Compliance Policy Guideline 460.200

After the Supreme Court's decision in *Western States*, the FDA issued a revised Compliance Policy Guideline ("CPG") that governed compounding and pharmacies. *See* CPG 460.200. Although CPG 460.200 is more specific than FDAMA, they contain similar provisions. *Wedgewood Village Pharmacy, Inc. v. United States*, 421 F.3d 263, 272 (3rd Cir. 2005). In the CPG, the FDA reiterates its long-standing position that it would not attempt to regulate traditional compounding practices. *See* CPG 460.200. Specifically, the CPG states the "FDA recognizes that pharmacists traditionally have extemporaneously compounded and manipulated reasonable quantities of human drugs upon receipt of a valid prescription for an individually identified patient from a licensed practitioner." *Id.* The CPG further states that this traditional compounding activity is not the subject of this guidance. *Id.* Rather, the CPG focuses on the regulation of pharmacies who manufacture drugs under the guise of compounding. *Id.* Pursuant to the CPG, the FDA shall consider nine different factors in deciding whether an enforcement action is appropriate for a pharmacy that claims it is compounding, but is actually manufacturing. *Id.* The language in CPG 460.200 demonstrates that the FDA draws a line between compounding for an individual patient pursuant to a prescription from a licensed practitioner and compounding that rises to the level of manufacturing. The Court finds this distinction further supports the exemption of compounded drugs from the new drug definitions, if the drugs are created for an individual patient on the basis of a prescription from a licensed practitioner.

d. 21 U.S.C. § 374

Another factor supporting the exemption of drugs that are compounded for an individual patient pursuant to a licensed practitioner's prescription is found in the Act under § 374. Section

374, examined in greater detail *infra*, provides the FDA with authority to inspect pharmacies to insure they are complying with the law. *See* 21 U.S.C. § 374. However, there is an explicit exemption from the inspection of all materials found in a pharmacy if the pharmacy is in compliance with local laws, dispensing drugs pursuant to a prescription from a licensed practitioner in the course of his or her professional practice, and compounding in the regular course of its business. *Id.* The Court finds this freedom from inspections of all materials for pharmacies that compound in the regular course of business demonstrates Congress' intent to carve out a niche for compounded drugs.

e. Public Policy

Finally, public policy supports exempting compounded drugs from the new drug definitions. If compounded drugs were required to undergo the new drug approval process, the result would be that patients needing individually tailored prescriptions would not be able to receive the necessary medication due to the cost and time associated with obtaining approval. When a licensed practitioner writes a prescription for a compounded drug for a patient, the medication is normally needed soon thereafter. It is not feasible, either economically or time-wise, for the needed medications to be subjected to the FDA approval process. It is in the best interest of public health to recognize an exemption for compounded drugs that are created based on a prescription written for an individual patient by a licensed practitioner.

f. Conclusion

In conclusion, this Court finds that compounded drugs, when created for an individual patient pursuant to a prescription from a licensed practitioner, are implicitly exempt from the new drug definitions contained in 21 U.S.C. §§ 321(p)(1) and (v)(1). Plaintiff's Motion for

Summary Judgment is granted on its claim that compounded drugs do not fall under the new drug definitions.

(2) Inspections

Plaintiffs next contend that they, as pharmacies who comply with 21 U.S.C. § 374(a)(2)(A), are exempt from inspections that exceed what is permitted by 21 U.S.C. § 374(a)(1). Further, they request the FDA be banned from bringing prosecutorial, enforcement or punitive actions against any Plaintiff for refusing to allow the FDA to conduct an inspection that exceeds the first sentence of 21 U.S.C. § 374(a)(1). In response, Defendants argue that the Act unequivocally authorizes the FDA to inspect pharmacies.

Section 374(a) of the Act provides that:

> "officers or employees designated by the Secretary....are authorized to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce;...and to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment....and all pertinent equipment, finished and unfinished materials, containers, and labeling therein."

See 21 U.S.C. § 374(a)(1). Additionally, the section provides:

> "[i]n the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, or restricted devices are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, or restricted devices which are adulterated or misbranded within the meaning of this chapter, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this chapter, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this chapter."

Id. This additional inspection authority is often referred to as the "records provision." *Wedgewood Vill. Pharmacy, Inc.*, 421 F.3d at 269. The records provision authorizes the FDA to search not just records, but any files, papers, processes, controls or facilities if a pharmacy is engaging in certain designated activities. *Id.* However, Congress has specifically exempted certain pharmacies from the enhanced inspection authority contained within the records provision. *Id.* The exemption provides:

> "(2) The provisions of the third sentence of paragraph (1) [the records provision] shall not apply to –
>
> (A) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail..."

Id. § 374(a)(2).

The first sentence of § 374 provides the FDA with a general inspection authority, while the records provision found in the third sentence allows the FDA to engage in enhanced inspections when pharmacies are adulterating or misbranding drugs or restricted devices or otherwise violating the Act. Congress created an exemption from the records provision, though, for pharmacies that (1) conform to applicable local laws that regulate pharmacy, (2) are regularly engaged in dispensing drugs or devices upon receipt of a prescription from a licensed practitioner in the course of his or her practice, and (3) only manufacture, prepare, propagate, *compound*, or process drugs or devices in the regular course of their business of dispensing or selling drugs at retail. *See id.* (emphasis added).

Pursuant to the language of § 374, the FDA has the authority to conduct limited inspections of all pertinent equipment, finished and unfinished materials, containers, and labeling found in pharmacies. However, if a pharmacy is compliant with local laws, and dispenses drugs pursuant to the receipt of a prescription from a licensed practitioner, and compounds in the regular course of its own individualized business, the pharmacy is exempt from the more detailed inspection of the records found in the third sentence of the section. In order to conduct a third sentence inspection of a pharmacy who meets the requirements found in the exemption, the FDA must demonstrate why the pharmacy does not qualify for the exemption.

In this case, the FDA has not demonstrated that any of the ten Plaintiff pharmacies do not qualify for the exemption. Rather, the evidence before the Court establishes that Plaintiff pharmacies all conform with the applicable local laws, dispense drugs pursuant to prescriptions from licensed practitioners and compound drugs in the regular course of their business. Because Plaintiff pharmacies meet the requirements of the exemption, the FDA cannot conduct inspections that exceed the authority granted in the first sentence of 21 U.S.C. § 374. In other words, the FDA is not authorized to carry out the more intrusive records inspection against Plaintiffs unless it demonstrates that they are no longer meeting the requirements set forth in the exemption.[3] Additionally, as long as the pharmacies involved in this case as Plaintiffs continue to meet the requirements of the exemption, the FDA shall not bring prosecutorial, enforcement or punitive actions against them for refusing to allow the FDA to conduct an inspection that exceeds the first sentence of 21 U.S.C. § 374(a)(1). Accordingly, Plaintiff's request for a declaration that the FDA is prohibited from compelling inspections that exceed the grounds set

[3] In making this ruling, the Court limits its holding to the pharmacies involved as Plaintiffs in this case, who have demonstrated that they each comply with the exemption requirements. The ruling does not extend to pharmacies who have not shown they meet the exemption.

forth in the first sentence of 21 U.S.C. § 374(a)(1) of pharmacies that comply with the requirements of 21 U.S.C. § 374(a)(2)(A) is granted only as to the pharmacies who are Plaintiffs in this cause of action.

(3) Compounding from Bulk Ingredients for Non-Food Animals

Plaintiffs maintain that nothing in the Act prohibits them from compounding drugs from bulk ingredients for non-food producing animals. Further, Plaintiffs declare this is an area of regulation for the states. In response, Defendants declare that the use of bulk active pharmaceutical ingredients in the compounding process as it relates to non-food producing animals creates a new drug that is unsafe, adulterated and misbranded under the Act.[4]

a. Unsafe and Adulterated Drugs

Defendants first contend that drugs compounded for non-food animals from bulk ingredients are unsafe under 21 U.S.C. § 360b, and hence adulterated under 21 U.S.C. § 351. Section 360b states "[a] new animal drug shall, with respect to any particular use or intended use of such drug, be deemed unsafe for purposes of section 351(a)(5) of this title unless..." certain requirements related to the filing of a new drug application are met. Section 351(a)(5) declares "[a] drug or device shall be deemed to be adulterated...if it is a new animal drug which is unsafe within the meaning of section 360b of this title."

As this Court declared in the discussion *supra*, compounded drugs do not fall within the new animal drug definition. Because drugs compounded for animal use are not new animal drugs, they do not fall under the provisions of 21 U.S.C. § 360b and thus are not unsafe.

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[4] Initially, Defendants maintained that the Animal Medicinal Drug Use Clarification Act of 1994 ("AMDUCA") prohibited compounding from bulk ingredients for animal drugs. At the summary judgment stage, however, Defendants abandoned this argument. Therefore, the Court shall not address this issue in depth, other than to recognize that AMDUCA does not prohibit the compounding of animal drugs from bulk-drug ingredients. Rather, AMDUCA permits the extra-label use of certain approved animal drugs.

Moreover, because animal drugs which have been compounded are not unsafe under 21 U.S.C. § 360b, they are not adulterated under 21 U.S.C. § 351.

b. Misbranded Drugs

Next, Defendants declare that drugs compounded from bulk ingredients for non-food animals are prohibited because bulk ingredients are drugs under 21 U.S.C. § 321(g)(1)(D) which are misbranded under 21 U.S.C. § 352. Defendants maintain the drugs are misbranded because they fail to bear adequate directions for use. However, as Defendants recognize in their Motion for Summary Judgment, there is an exemption found in the Regulations relating to the use of bulk ingredients. The regulation found at 21 C.F.R. § 201.122 exempts bulk ingredients from the Act's adequate directions for use requirement unless the finished product is a new drug. This Court found *supra* that drugs compounded for animal use are not new drugs. Thus, 21 C.F.R. § 201.122 exempts the bulk ingredients used in compounding drugs for non-food animals. As such, the Court finds that the Act does not contain a prohibition that prevents the use of bulk ingredients in drugs compounded for non-food animals.

Additionally, the Court finds it should be noted that the misbranding provision found in 21 U.S.C. § 352 does not automatically apply to Plaintiff pharmacies in this case because the evidence demonstrates they are:

> "pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail..."

21 U.S.C. § 360(g)(1). Because Plaintiff pharmacies are compliant, they are not required to register with the Secretary nor are they automatically subject to the misbranding provision. *See* 21 U.S.C. § 352(o).

c. *Containers* and *Algon*

Finally, the parties debate at length whether the cases of *United States v. 9-1 Kg. Containers*, 854 F.2d 173 (7th Cir. 1988) and *United States v. Algon Chem., Inc.*, 879 F.2d 1154 (3rd Cir. 1989) prevent pharmacies that are deemed compliant under 21 § U.S.C. 360(g)(1) from compounding using bulk ingredients. After duly considering both cases, this Court finds that *Containers* and *Algon* are distinguishable from the case now before it. Those cases involved bulk drug suppliers who were providing bulk drugs directly to veterinarians. Suppliers and veterinarians are not afforded the protections that compliant, compounding pharmacies are given under the Act. As long as compliant pharmacies are compounding drugs for non-food animals with legal bulk ingredients, they comport with the Act. That is the case with Plaintiffs in this case, who are all compliant pharmacies. If, however, pharmacies use illegal bulk ingredients when compounding for non-food animals, they lose the protections afforded by the Act and are subject to enforcement actions.

d. Conclusion

In conclusion, this Court finds that pharmacies may compound drugs for non-food animals from legal bulk ingredients. Drugs compounded from legal bulk ingredients do not violate the Act's unsafe, adulterated or misbranded provisions. Plaintiffs' Motion for Summary Judgment is accordingly granted on this claim.

(4) Compliance Policy Guideline 608.400 and the Notice

Plaintiffs assert that the CPG and Notice at issue in this case misstate the law and violate the Administrative Procedures Act. To the contrary, Defendants contend that the CPG and the Notice are not substantive rules and therefore do not require notice and comment rulemaking. The specific CPG about which Plaintiffs complain in this case is CPG 608.400. CPG 608.400 prohibits the compounding of drugs for non-food animals from bulk ingredients. The Notice at issue was sent on April 2, 2004, to all United States Boards of Pharmacy from the Director of the Office of Compliance for the FDA Center for Veterinary Medicine. The Notice declared that pharmacy compounding from bulk ingredients for non-food animals is illegal.

The Administrative Procedures Act requires that substantive or legislative rules, which have the force and effect of law, are subject to the APA's notice-and-comment rulemaking requirements. *See* 5 U.S.C. § 553(b). Exempt from the notice-and-comment requirements are "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice." 5 U.S.C. § 553(b)(A). However, "if a rule is 'substantive,' the exemption is inapplicable, and the full panoply of notice-and-comment requirements must be adhered to scrupulously. The 'APA's notice and comment exemptions must be narrowly construed.'" *Prof'ls and Patients for Customized Care v. Shalala*, 56 F.3d 592, 595 (5th Cir. 1995). Courts of the Fifth Circuit have long recognized that CPG's are not substantive rules, and thus are exempt from the notice-and-comment requirements. *See Prof'ls and Patients for Customized Care; Se. Minerals, Inc. v. Harris*, 622 F.2d 758 (5th Cir. 1980); and *Cowdin v. Young*, 681 F.Supp. 366, 370 (W.D. La. 1987).

After careful consideration of CPG 608.400 and the Notice, this Court finds that they are not substantive rules. The CPG clearly states that it is not binding on the FDA or the public, and

that it merely reflects the FDA's current thinking on what might be subject to an enforcement action. Similarly, the Notice was issued to the States as a request for assistance with potential FDA inspections of pharmacies. The Court finds that neither of these documents contain new substantive rules, and thus neither were subject to the APA's notice-and-comment procedures.

However, despite the fact that CPG 608.400 and the Notice were not subject to notice-and-comment, and therefore will neither will be stricken, the Court finds that they do not fully comport with the instant Order. To the extent that they contradict the rulings contained herein, the FDA shall no longer be permitted to enforce those portions of CPG 608.400 and the Notice. The balance of the CPG and the Notice shall remain in effect. Thus, the Defendants' Motion for Summary Judgment is granted in part, as the Court finds the CPG and Notice were not subject to the APA's notice-and-comment procedures. Plaintiffs' Motion for Summary Judgment is granted in part, as the Defendants shall no longer be permitted to enforce the portions of the CPG and Notice which conflict with the instant Order.

(5) Injunctions

Plaintiffs have requested injunctions against Defendants to prevent them from (1) declaring that compounded drugs are new drugs or new animal drugs, (2) engaging in inspections that exceed the subjects enunciated in the first sentence of 21 U.S.C. § 374(a)(1) of pharmacies that are in good standing with their respective State boards of pharmacy and have met the Exemption Criteria, (3) enforcing its current Compliance Policy Guideline which unilaterally declares that compounding from bulk ingredients for non-food animals is illegal, (4) prohibiting Plaintiffs or similarly situated pharmacies from receiving bulk ingredients, and (5) bringing prosecutorial, enforcement or punitive actions against any Plaintiffs for refusing to allow the FDA to conduct inspections exceeding the first sentence of 21 U.S.C. § 374(a)(1) of

their pharmacies, pursuant to 21 U.S.C. § 374(a)(2)(A), absent independent evidence from the relevant State boards of pharmacy that Plaintiffs are non-compliant. Defendants, in response, argue that there is no legal or factual basis to support the entering of any injunction in this case.

At this time, the Court finds that it is not appropriate to enter injunctions that would amount to pre-enforcement review of FDA actions. *See Southeastern Minerals, Inc. v. Harris*, 622 F.2d 758 (5th Cir. 1980). However, the parties are advised that Plaintiffs' requests for injunctions are denied without prejudice. If in the future Defendants continue to violate the Act, Plaintiffs may re-urge their requests for injunctions and the Court shall consider the petition at that time. Therefore, Plaintiffs' requests for an injunction, contained within their Motion for Summary Judgment, is denied without prejudice. Defendants' request that the injunctions be denied is granted, with the caveat that Plaintiffs shall be permitted to resubmit their requests for injunctions if Defendants continue to violate the Act.

CONCLUSION

Based on the above-stated reasoning, Plaintiffs' Motion for Summary Judgment is granted in part and denied in part, and Defendants' Motion for Summary Judgment is granted in part and denied in part. Accordingly,

It is **HEREBY ORDERED** that Plaintiffs' Motion Summary Judgment is **GRANTED IN PART.**

It is **FURTHER ORDERED** that Plaintiffs' Motion for Summary Judgment is **DENIED IN PART,** in that the requests for injunctions are denied without prejudice.

It is **FURTHER ORDERED** that Defendants' Motion for Summary Judgment is **GRANTED IN PART AND DENIED IN PART.**

SIGNED this 30 day of **AUGUST, 2006.**

ROBERT JUNELL
United States District Judge
Western District of Texas

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

To: Licensing Committee

Date: September 7, 2006

From: Board of Pharmacy

Subject: Competency Committee Report

Exam Result Delay

Periodically, the Board of Pharmacy performs quality assurance assessments to ensure the appropriateness of the California Pharmacist Jurisprudence Examination (CPJE). The board initiated such a study on August 14, 2006. To assure the thoroughness of this assessment, approximately 400 individuals will be needed for participation. Based on the number of candidates who took the CPJE last year during this same period, the board anticipates releasing scores by the end of September 2006.

Once the quality assurance has been completed, release of examination scores should resume on a weekly basis, usually within 14 days after a candidate takes the examination.

Test Administration Contract

The Office of Examination Resources (OER) within the Department of Consumer Affairs is seeking a new contract with a vendor to provide computer based testing through a Request for Proposal (RFP) process. The board uses this contract to administer the CPJE statewide. The current contract expires December 1, 2006.

In December 2005, the department released a RFP for computer-based testing. However, several months into 2006, this process was ended after a protest from one of the unsuccessful bidders was filed.

The department has since worked the RFP and released a new RFP on July 13, 2006. Final proposals are due to the Department of Consumer Affairs by September 13, 2006, with an anticipated contract award date of October 20, 2006. New services resulting from the RFP process are tentatively scheduled to begin in April 2007.

Annual Meeting

The Competency Committee met on August 3 and 4, 2006, for its annual meeting. The purpose of the annual meeting was to focus on long-term goals of the committee as well as to review the examination process to make improvements. The committee structure was bifurcated at the meeting to increase the efficiency of the examination development.

CPJE Pass Rate

Detailed statistical reports for the CPJE and NAPLEX are provided to the board in October and April.

The statistical report due to the board for the October meeting will be provided in the October 2006 board packet.

Once provided to the board, copies of these reports can be found at http://www.pharmacy.ca.gov/about/pass_rates.htm.